



No.F.4-1/2024-MD (M-65)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 1st April 2024

Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO IMPORT – SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF.**

The applications of following applicants were considered by Medical Device Board (MDB) in its 65th meeting held on 25th & 26th January, 2024 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:-

S.#	Firm Details	Manufacturer Details	Name of Medical Device/ Class/Shelf life / Codes etc	Decision of MDB
(I)	(II)	(III)	(IV)	(V)
1.	M/s Biologic Medical Systems, Karachi. ELI-00346	Legal Manufacturer & Site: Huntleigh Healthcare Ltd. 35 Portmanmoor road, Cardiff CF24 5HN, UNITED kingdom. Copy of FSC issued by MHRA dated 28-01-2019. Copy of ISO 13485 valid upto 30-04-2022 Copy of EC/FQA Certificate valid upto 30-09-2020. LOA valid upto 11-02-2021	Huntleigh Sonicaid Team 3 Fetal Monitor Codes & Sizes: TEAM 3A & TEAM 3I. Class-C Shelf Life : NA Fee: 50,000/- Date of Application: 27-02-2020	Deferred for submission of the following: - <ul style="list-style-type: none">Valid notarized Letter of Authorization (LOA)Valid Notarized ISO13485 & EC/FQAApply separately for TEAM 3I with fresh application & fee.
2.	M/s Cardio Life, House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi ELI: 00984 [3645-P]	Legal Manufacturer: M/s CPT Sutures Co., Ltd , 83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam. Manufacturing Facility 8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam. Legalized FSC Vietnam valid upto 25-09-2023. Notarized Copy of ISO 13485 valid upto 30-09-2024. LOA valid upto 31-12-2024	Protibond Polyester Non-absorbable Surgical Suture Codes & Sizes: Class-D Shelf Life :5 years Fee: 50,000/- Date of Application: 15-02-2023	Deferred for submission of the following: - <ul style="list-style-type: none">Valid embassy attested Free Sale Certificate of reference country or valid notarized copy of EC/FQA.Valid Notarized Design Examination Certificate

3.	M/s Cardio Life, House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi ELI: 00984 [3645-P]	<p>Legal Manufacturer: M/s CPT Sutures Co., Ltd, 83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam.</p> <p>Manufacturing Facility 8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam.</p> <p>Legalized FSC Vietnam valid upto 25-09-2023.</p> <p>Notarized Copy of ISO 13485 valid upto 30-09-2024.</p> <p>LOA valid upto 31-12-2024</p>	<p>Trustilent Polypropylene Non-Absorbable Surgical Suture</p> <p>Codes & Sizes: Class-D</p> <p>Shelf Life :5 years</p> <p>Fee: 50,000/-</p> <p>Date of Application: 15-02-2023</p>	<p>Deferred for submission of the following: -</p> <ul style="list-style-type: none"> Valid embassy attested Free Sale Certificate of reference country or valid notarized copy of EC/FQA. Valid Notarized Design Examination Certificate
4.	M/s Cardio Life, House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi ELI: 00984 [3645-P]	<p>Legal Manufacturer: M/s CPT Sutures Co., Ltd, 83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam.</p> <p>Manufacturing Facility 8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam.</p> <p>Legalized FSC Vietnam valid upto 25-09-2023.</p> <p>Notarized Copy of ISO 13485 valid upto 30-09-2024.</p> <p>LOA valid upto 31-12-2024</p>	<p>Caresteel Surgical Stainless Steels-Non-absorbable Surgical Suture</p> <p>Codes & Sizes: Class-C</p> <p>Shelf Life :5 years</p> <p>Fee: 50,000/-</p> <p>Date of Application: 15-02-2023</p>	<p>Deferred for submission of the following: -</p> <ol style="list-style-type: none"> Valid embassy attested Free Sale Certificate of reference country or valid notarized copy of EC/FQA.
5.	M/s Cardio Life, House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi ELI: 00984 [3645-P]	<p>Legal Manufacturer: M/s CPT Sutures Co., Ltd, 83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam.</p> <p>Manufacturing Facility 8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam.</p> <p>Legalized FSC Vietnam valid upto 25-09-2023.</p> <p>Notarized Copy of ISO</p>	<p>Carecel Absorbable Hemostats</p> <p>Codes & Sizes: Class-D</p> <p>Shelf Life :5 years</p> <p>Fee: 50,000/-</p> <p>Date of Application: 15-02-2023</p>	<p>Deferred for submission of the following:-</p> <ul style="list-style-type: none"> Valid embassy attested Free Sale Certificate of reference country or valid notarized copy of EC/FQA. Valid Notarized Design Examination Certificate

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		13485 valid upto 30-09-2024. LOA valid upto 31-12-2024		
6.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156	Legal Manufacturer: M/s Bio-Rad , 3 Boulevard Raymond Poincare, 92430 Marnes, la Conquette, France. Site: Bio Rad, Route de Cassel-59114 Steenvoorde France. Lagalized FSC issued by CCI Paris France dated 28-07-2022. Notarized copy of ISO 13485 valid upto 11-12-2024 Distribution Certificate valid upto 31-12-2023	Platelia Aspergillus Aspergillus fumigatus IgG Antibody IVD kit enzyme Immunoassay EIA Codes & Sizes: 62783 Class-C Shelf Life : 18 months Fee: 50,000/- Date of Application: 16-02-2023	Deferred for submission of the following: - • Valid notarized Letter of Authorization (LOA)
7.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156	Legal Manufacturer: M/s Bio-Rad , 3 Boulevard Raymond Poincare, 92430 Marnes, la Conquette, France. Site: Bio Rad, Route de Cassel-59114 Steenvoorde France. Lagalized FSC issued by CCI Paris France dated 28-07-2022. Notarized copy of ISO 13485 valid upto 11-12-2024 Distribution Certificate valid upto 31-12-2023	Platelia Aspergillus Ag Aspergillus species galactomannan antigen IVD Kit EIA Codes & Sizes: 64794 Class-C Shelf Life : 12 months Fee: 50,000/- Date of Application: 16-02-2023	Deferred for submission of the following: - • Valid notarized Letter of Authorization (LOA)
8.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156	Legal Manufacturer: M/s Bio-Rad , 3 Boulevard Raymond Poincare, 92430 Marnes, la Conquette, France. Site: Bio Rad, Route de Cassel-59114 Steenvoorde France. Lagalized FSC issued by CCI Paris France dated 28-07-2022. Notarized copy of ISO 13485 valid upto 11-	Pastorex meningitis Multiple meningitis associated bacteria antigen IVD Kit agglutination. Codes & Sizes: 61607, 61608, 61610, 61611, 61613, 61614, 61616, 61618 Class-C Shelf Life : 12 months Fee: 50,000/-	Deferred for submission of the following: - • Valid notarized Letter of Authorization (LOA)

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		12-2024 Distribution Certificate valid upto 31-12-2023	Date of Application: 16-02-2023	
9.	M/s Chemical House, 6C Skinder Malhi Road, Canal Park Gulerg II, Lahore ELI: 00156	Legal Manufacturer/Manufacturer: M/s Exact Diagnostics LLC, 100 South Jones Street Suit 100 fort Worth Texas 76104 USA Copy of FSC: USA Valid till: 23/05/2023 Copy of ISO 13485 valid upto 26-05-2025 Notarized copy of EC Certificate- Full Quality Assurance valid upto 26-05-2025. Notarized copy of Design Examination Certificate- valid upto 26-05-2025.	Exact Diagnostics HCV RUN Controls (Exactdiagnostics HCV low run control HCVL 101 & Exact diagnostics High Run Control HCVH102) (External quality control, Unassayed) Codes & Sizes: As mentioned above. Class: D Shelf Life: 36 months Fee: 50000 Date of Submission of Application: 13/09/2023	Deferred for submission of the following: - <ul style="list-style-type: none"> Apply separately for high run control with fresh application & fee. Clarification of the difference in the legal manufacturer /manufacturer as per provided Form-7A & FSC. Valid notarized Letter of Authorization (LOA) issued by product license holder/legal manufacturer/ Authorized person. Valid Free Sale Certificate.
10.	M/s Chemical House, 6C Skinder Malhi Road, Canal Park Gulerg II, Lahore ELI: 00156	Legal Manufacturer/Manufacturer: M/s Exact Diagnostics LLC, 100 South Jones Street Suit 100 fort Worth Texas 76104 USA Copy of FSC: USA Valid till: 23/05/2023 Copy of ISO 13485 valid upto 26-05-2025 Notarized copy of EC Certificate- Full Quality Assurance valid upto 26-05-2025. Notarized copy of Design Examination Certificate- valid upto 26-05-2025.	Exact Diagnostics Negative Control (negative run control NEG000, Bul negative NEG050, HAI negative run control NEGHAI, Synthetic Negative run control NEGSYN) [External quality Run control for various molecular assay] Codes & Sizes: As mentioned above Class: D Shelf Life: 24-36 months Fee: 50000 Date of Submission of Application: 13/09/2023	Deferred for submission of the following: - <ul style="list-style-type: none"> Apply separately for different controls with fresh application & fee. Clarification of the difference in the legal manufacturer /manufacturer as per provided Form-7A & FSC. Valid notarized Letter of Authorization (LOA) issued by product license holder/legal manufacturer/Authorized person. Valid Free Sale Certificate.
11.	M/s Chemical House, 6C Skinder Malhi Road, Canal Park Gulerg II, Lahore ELI: 00156	Legal Manufacturer/Manufacturer: M/s Exact Diagnostics LLC, 100 South Jones Street Suit 100 fort Worth Texas 76104 USA	Exact Diagnostics HIV-I, HBV, HCV Screen control (Exact diagnostics HBV DNA screen control HIBVSCREEN, Exact diagnostics HCV RNA screen control)	Deferred for submission of the following: - <ul style="list-style-type: none"> Apply separately for high run control with fresh application & fee. Clarification of the difference in the legal manufacturer /manufacturer as

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		<p>Copy of FSC issued by CCI Paris France dated 11-10-2022.</p> <p>ISO 13485 valid upto 26-05-2025</p> <p>Notarized copy of EC Certificate- Full Quality Assurance valid upto 26-05-2025.</p> <p>Notarized copy of Design Examination Certificate- valid upto 26-05-2025.</p>	<p>HCVSCREEN, Exact diagnostics HIV-I screen control HIVSCREEN, Exact diagnostics HIV,HBV, HCB screen control VIRSCREEN.</p> <p>(External Quality control, unassayed) Codes & Sizes: As mentioned above</p> <p>Class:D Shelf Life: 18 months</p> <p>Fee: 50000</p> <p>Date of Submission of Application: 13/09/2024</p>	<p>per provided Form-7A & FSC.</p> <ul style="list-style-type: none"> Valid notarized Letter of Authorization (LOA) issued by product license holder/legal manufacturer/ Authorized person. Valid Free Sale Certificate.
12.	<p>M/s Chemical House, 6C Skinder Malhi Road, Canal Park Gulerg II, Lahore</p> <p>ELI: 00156</p>	<p>Legal Manufacturer/ Manufacturer:</p> <p>M/s Exact Diagnostics LLC, 100 South Jones Street Suit 100 fort Worth Texas 76104 USA</p> <p>Copy of FSC: USA Valid till: 23/05/2023</p> <p>Copy of ISO 13485 valid upto 26-05-2025</p> <p>Notarized copy of EC Certificate- Full Quality Assurance valid upto 26-05-2025.</p> <p>Notarized copy of Design Examination Certificate- valid upto 26-05-2025.</p>	<p>Exact Diagnostics HBV Run Controls (Exact diagnostics HBV low run control HBVL101 & Exact diagnostics High run control HBVH102)</p> <p>[External Quality control, Unassayed)</p> <p>Codes & Sizes: As mentioned above</p> <p>Class-D</p> <p>Shelf Life: 36 months Fee: 50000</p> <p>Date of Submission of Application: 13/09/2024</p>	<p>Deferred for submission of the following: -</p> <ul style="list-style-type: none"> Apply separately for high run control with fresh application & fee. Clarification of the difference in the legal manufacturer /manufacturer as per provided Form-7A & FSC. Valid notarized Letter of Authorization (LOA) issued by product license holder/legal manufacturer/Authorized person. Valid Free Sale Certificate.
13.	<p>M/s Chemical House, 6C Skinder Malhi Road, Canal Park Gulerg II, Lahore</p> <p>ELI: 00156</p>	<p>Legal Manufacturer/ Manufacturer:</p> <p>M/s Exact Diagnostics LLC, 100 South Jones Street Suit 100 fort Worth Texas 76104 USA</p> <p>Original FSC: USA Valid till: 17/11/2023</p> <p>ISO 13485 valid upto 26-05-2025</p> <p>Notarized copy of EC Certificate- Full Quality Assurance valid upto</p>	<p>Exact Diagnostics HIV-I RUN Controls (Exact diagnostics HIV low run control HIVL101 & Exact diagnostics HIV High run control HIVH 102)</p> <p>External Quality Control, Unassayed.</p> <p>(External Quality control, Unassayed) Codes & Sizes: As mentioned above</p> <p>Class:D Shelf Life: 36 months</p>	<p>Deferred for submission of the following: -</p> <ul style="list-style-type: none"> Apply separately for high run control with fresh application & fee. Clarification of the difference in the legal manufacturer /manufacturer as per provided Form-7A & FSC. Valid notarized Letter of Authorization (LOA) issued by product license holder/legal manufacturer/Authorized person. Valid Free Sale Certificate.

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		26-05-2025. Notarized copy of Design Examination Certificate- valid upto 26-05-2025.	Fee: 50000 Date of Submission of Application: 13/09/2023	
14.	M/s Chemical House, 6C Skinder Malhi Road, Canal Park Gulerg II, Lahore ELI: 00156	Legal Manufacturer/Manuf actuer: M/s Exact Diagnostics LLC, 100 South Jones Street Suit 100 fort Worth Texas 76104 USA Copy of FSC: USA Valid till: 23/05/2023 Copy of ISO 13485 valid upto 26-05-2025 Notarized copy of EC Certificate- Full Quality Assurance valid upto 26-05-2025. Notarized copy of Design Examination Certificate- valid upto 26-05-2025.	Exact Diagnostics Low Run control CMVL101, Exact diagnostics CMV high run control CMVH102 Codes & Sizes: As mentioned above Class:C Shelf Life: 36 months Fee: 50000 Date of Submission of Application: 13/09/2024	Deferred for submission of the following: - <ul style="list-style-type: none"> Apply separately for high run control with fresh application & fee. Clarification of the difference in the legal manufacuer /manufacturer as per provided Form-7A & FSC. Valid notarized Letter of Authorization (LOA) issued by product license holder/legal manufacturer/Authorized person. Valid Free Sale Certificate.
15.	M/s Cardiac Care, 848-C, Shadman-1, Lahore ELI: 00070	Legal Manufacturer: Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA, Manufacturing Site: Edwards Lifesciences (Singapore) Ptd Ltd 35 Changi North Crescent Singapore 499641 Singapore Copy of ISO 13485 valid upto 07-01-2024 FSC No.6546-3-2022 issued by USA valid upto 21-03-2024.	Inspiris Resilia Aortic Valve (Aortic Valve) Class-D Shelf Life: 5 years Codes & Sizes: As per FSC LoA valid 31 Dec 2023 DE valid 26 May 2024 FQA valid 26 May 2024	Deferred for submission of the following: - <ul style="list-style-type: none"> Valid notarized Letter of Authorization (LOA) Valid ISO13485
16.	M/s Global Clinical Cura, 18, Mian Iqbal Road Westridge 1, Rawalpindi ELI: 00196 [3724]	Legal Manufacturer: M/s Beijing Wantai Biological Pharmacy Enterprises Co., Ltd, No. 31 Kexueyuan Road Changping District Beijing P.R China	Diagnostic kit for T cell infected with Mycobacterium Tuberculosis (TB-IGRA) Codes & sizes: Class-C	Deferred for submission of the following: - <ul style="list-style-type: none"> Valid embassy attested Free Sale Certificate of reference country or valid notarized copy of EC/FQA. Valid Free Sale Certificate of country of origin.

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		FSC:China Valid till: 2023/03/22. ISO 13485 valid upon 18-01-2025	Shelf Life: 12 months Fee: 50000 Date of Application: 02-02-2023	
17.	M/s Future D Pakistan, House No. 482-G-3, Johar Town, Lahore ELI: 00568 2473-P	Legal Manufacturer: Novodent SA Y.PARC Technopole, Avenu des Sciences 11, CH-1400 Yverdon-les- Bains, Switzerland. FSC: Swismedic (Switzerland) Valid till: 12.03.2024. Copy of Authorization letter valid upto 23-12- 2021. Copy of EC Certificate (FQA) valid upto 27- 05-2024.	Implantswiss Tissue Level Dental Implant system (Dental implant System and components, Surgical Drill) Class-C Shelf life: 5 years (for dental implant) Codes: Tissue Level Implants, Abutments, Screws, Solid Caps, Common Components for Tissue Level Implants, Dental drills.	Deferred for submission of the following: - • Apply separately for each type of Dental implant (i.e. Tissue Level Implants, Abutments, Screws, Solid Caps, Common Components for Tissue Level Implants, Dental drills.) with fresh application & fee. • Valid notarized Letter of Authorization (LOA)
18.	M/s EASHA ENTERPRISE S Office No. 376, Pak Khalij Medical Center, Saidpur Road Rawalpindi ELI:00203	Legal Manufacturer Hemotec Medical GmbH Beckelmannsweg 10 D- 46342 Velen (Germany) Appointment of Exclusive Distributor agreement valid upto 30-03-2023. Copy of ISO 13485 expired on 06-09-2021. Copy of EC- Certificate (FQA) valid upto 28- 01-2028	Starsil Hemostate Powder Polysaccharide powder Class-D Shelf Life: 3 years FEE: 50000 Code/pack size: (1g,2g,3g,5g)	Deferred for submission of the following: - • Valid notarized Letter of Authorization (LOA). • Valid ISO13485. • Embassy Attested FSC • Notarized copy of Design Examination Certificate
19.	M/s De Khon, 11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317	Legal Manufacturer/ Manufacturer (As per FSC): Iromed Group S.R.L. Via Tempio del Cielo, 3/5 - 00144 Roma (RM) Italy. Manufacturer (As per Form-7A): SERVImed Industrial S.p.A. with registered office at Via Tempio del Cielo 3/5, 00144 Rome, Italy FSC: Italy	Droptonic 5% sterile Composition (%w/w) Sodium Hyaluronate..0.1 Sodium Chloride..4.76 Sodium monobasic phosphate monohydrate..0.066 Dibasic sodium phosphate dodecahydrate..0.315 L-proline Ph.Eur.0.001 L-glycine USP..0.001 L-lysine HCl Ph.Eur..0.0005 L-leucine USP..0.0008 Riboflavin Sodium hosphate..0.0750 Vitamin E-TPGS..0.5 Purified water	Deferred for submission of the following: - • Referred the case to PE&R division for comments regarding the product status as drug or otherwise. • Clarification regarding the difference in the address of manufacturer in Form-7A & FSC. • Valid FQA/CE Certificate

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		dated 21-01-2023 Notarized copy of ISO 13485 valid upto 02-10-2024 Notarized copy of EC Certificate- Full Quality Assurance valid upto 27-02-2023.	(q.b.a)..100 Code/Pack size: 10ml Class C Fee submitted Rs.25,000+25,000 Free sale certificate submitted Shelf life: 36 months Date of Application : 11-05-2023	
20.	M/s De Khon, 11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317	Legal Manufacturer/ Manufacturer (As per FSC): Iromed Group S.R.L. Via Tempio del Cielo, 3/5 - 00144 Roma (RM) Italy. Manufacturer (As per Form-7A): SERVImed Industrial S.p.A. with registered office at Via Tempio del Cielo 3/5, 00144 Rome, Italy FSC: Italy dated 21-01-2023. Notarized copy of ISO 13485 valid upto 02-10- 2024 Notarized copy of EC Certificate- Full Quality Assurance valid upto 26-05-2024.	Droptonic 5% sterile Composition (g/100g) Chlorexidine digluconate (20%)..0.02g Sodium Chloride..0.66g Sodium phosphate monobasic monohydrate ..0.15g Sodium phosphate Bibasic..0.40 Vitamin E-TPGS...0.20g Purified water (q.b.a)..100g Code/Pack size: 10ml Class C Fee submitted Rs.25,000+25,000 Shelf life: 24 months Date of Application : 11- 05-2023	Deferred for submission of the following:- • Referred the case to PE&R division for comments regarding the product status as drug or otherwise. • Clarification regarding the difference in the address of manufacturer in Form-7A & FSC. • Valid FQA/CE Certificate
21.	M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3721 Submission date: 25/01/2023 Fee submitted: 50,000/- Challan No. 8313838062	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Address: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC:USA Valid till: 20/07/2023	MetriQ™ Pump,RF Cardiac Ablation System (irrigation pump, roller) Codes & sizes: M00441000 Class-C	Deferred for the provision of following: • The manufacturing site Address: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 is not mentioned on credentials of manufacturer. • LOA is expired on 31-12-2022. • The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please. • FSC (USA) expired on 20/07/2023 but valid upon submission. Provide Valid FSC. • ISO Certificate expired on

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				01/09/2023 but valid upon submission. Provide Valid ISO Certificate.
22.	M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3900 Submission date: 10/04/2023 Fee submitted: 50,000/- Challan No. 4737766993	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN, USA 55112 FSC: USA 12/10/2024	Momentum EL-ICD (Implantable cardioverter Defibrillator) Codes & sizes: models: D120, D121 Class:D Shelf Life: 2 years	Deferred for the provision of following: <ul style="list-style-type: none">The manufacturing site Address: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 is not mentioned on credentials of manufacturer.LOA is expired on 31-12-2023.The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please.Provide Valid ISO Certificate.
23.	M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3901 Submission date: 10/04/2023 Fee submitted: 50,000/- Challan No. 380583560	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC: USA Valid till: 23/06/2024	Momentum CRT-D (Cardiac Resynchronization Therapy Defibrillator) Codes & sizes: models: G124 G125 G126 Class:D Shelf Life: 2 years	Deferred for the provision of following: <ul style="list-style-type: none">The manufacturing site Address: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 is not mentioned on credentials of manufacturer.LOA is expired on 31-12-2023.The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please.Provide Valid ISO Certificate.
24.	M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3909 Submission date: 03/05/2023 Fee submitted: 50,000/- Challan No. 25977867082	Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112 USA Manufacturing Sites: 1) Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112 USA 2) Boston Scientific Corporation Cashel Road Clonmel Tipperary, Ireland 3) Boston Scientific Corporation NO.12 RD. No. 698 Dorado, PR USA 00646 Original FSC: U.S.A Valid till: 29/09/2023	Emblem™ S-ICD System (Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)) Codes & sizes: models: Emblem S-ICD Subcutaneous Electrode Model:3501 Class-D Shelf Life: 02 Years	Deferred for the provision of following:- <ul style="list-style-type: none">The Legal Manufacturer & manufacturing sites Address: 1) Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112,Boston Scientific Corporation Cashel Road Clonmel Tipperary, IrelandBoston Scientific Corporation NO.12 RD. No. 698 Dorado, PR USA 00646 are not mentioned on credentials of manufacturer.The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please.LOA is expired on 31-12-2023.

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				<ul style="list-style-type: none"> • Provide Valid ISO Certificate • FSC (USA) expired on 29/09/2023 but valid upon submission. Provide Valid FSC. • Submit separate case with separate fee of 50,000/-PKR for Emblem S-ICD Electrode Delivery System Model: 4712 & Emblem MRI S-ICD Model: 219.
25.	M/s Feroszons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3910 Submission date: 03/05/2023 Fee submitted: 50,000/- Challan No. 5522830287	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica FSC: U.S.A Valid till: 20/07/2023	IntellaNav™ ST Ablation Catheters (Catheter, Cardiac Ablation) Codes & sizes: M004R5031TH0 M004R5031THK20 Class-D Shelf Life: 03 Years	Deferred for the provision of following:- <ul style="list-style-type: none"> • The manufacturing site Address: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica is not mentioned on credentials of manufacturer. • The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please. • LOA is expired on 31-12-2023. • Provide Valid ISO Certificate • FSC (USA) expired on 20/07/2023 but valid upon submission. Provide Valid FSC.
26.	M/s Feroszons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3911 Submission date: 03/05/2023 Fee submitted: 50,000/- Challan No. 37973886907	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica FSC: U.S.A Valid till: 20/07/2023	IntellaNav™ MiFi OI Ablation Catheters (Catheter, Cardiac Ablation) Codes & Sizes: M004PMR96200 M004PMR9620K20 M004PMR9620N40 Class-D Shelf Life: 02 Years	Deferred for the provision of following:- <ul style="list-style-type: none"> • The manufacturing site Address: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica is not mentioned on credentials of manufacturer. • The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please. • LOA is expired on 31-12-2023. • Provide Valid ISO Certificate • FSC (USA) expired on 20/07/2023 but valid upon submission. Provide Valid FSC.
27.	M/s Feroszons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3912	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation	IntellaTip MiFi™ Open-Irrigated Ablation Catheters (Catheter, Cardiac Ablation) Codes & Sizes: M004PM96200 M004PM9620K20 M004PM9620N40 Class-D	Deferred for the provision of following:- <ul style="list-style-type: none"> • The manufacturing site Address: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica is not mentioned on credentials of manufacturer. • The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi)

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	Submission date: 03/05/2023 Fee submitted: 50,000/- Challan No. 9461769669	302 Parkway, Global Park La Aurora, Heredia Costa Rica Original FSC: U.S.A Valid till: 20/07/2023	Shelf Life: 03 Years	is different from address mentioned on form-4 (establishment license). Clarify please. <ul style="list-style-type: none"> • LOA is expired on 31-12-2023. • Provide Valid ISO Certificate • FSC (USA) expired on 20/07/2023 but valid upon submission. Provide Valid FSC.
28.	M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3720 Submission date: 16/02/2023 Fee submitted: 50,000/- Challan No. 885927282412	Legal Manufacturer: Boston Scientific Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation, 4100 Hamline Avenue North St. Paul, MN 55112 USA FSC: USA Valid till: 22/07/2023	LABSYSTEM™ PRO EP Recording System and CLEARSIGN™/CLEARSIGN™ II Amplifier (single-patient physiological monitoring system) Codes & Sizes: M00420020230 LABSYSTEM™ PRO EP Recording System, CLEARSIGN II Amplifier for LABSYSTEM PRO EP Recording System, 120 Channels. M00420012500 LABSYSTEM PRO EP Recording System 40-Channel IC Junction Box for CLEARSIGN Amplifier, 3m M00420012300 LABSYSTEM PRO EP Recording System RF Filter Module for CLEARSIGN Amplifier M00420020210 LABSYSTEM PRO EP Recording System, CLEARSIGN II Amplifier for LABSYSTEM PRO EP Recording System, 40 Channels Class: C Shelf life: N/A	Deferred for the provision of following:- <ul style="list-style-type: none"> • The manufacturing site Address: Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112 USA is not mentioned on credentials of manufacturer. • The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please. • LOA is expired on 31-12-2023. • Provide valid FSC (USA). • Submit separate case with separate fee of 50,000/-PKR for each product i.e., M00420012500 LABSYSTEM PRO EP Recording System 40-Channel IC Junction Box for CLEARSIGN Amplifier, 3m M00420012300 LABSYSTEM PRO EP Recording System RF Filter Module for CLEARSIGN Amplifier M00420020210 LABSYSTEM PRO EP Recording System CLEARSIGN II Amplifier for LABSYSTEM PRO EP Recording System, 40 Channels • ISO Certificate expired on 20/10/2023 but valid upon submission.
29.	M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3899 Submission date: 10/04/2023 Fee submitted:	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC: USA	Momentum X4 CRT-D (cardiac Resynchronization therapy defibrillator) Codes & Sizes: Models: G128 G138 Class: D Shelf Life: 2 years	Deferred for the provision of following:- <ul style="list-style-type: none"> • The manufacturing site Address: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica is not mentioned on credentials of manufacturer. • The distributor address mentioned on LOA (Feroszons Laboratories Limited, 197A the mall Rawalpindi) is different from address mentioned on form-4 (establishment license). Clarify please.

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	50,000/- Challan No. 800711787	Valid till: 23/06/2024		<ul style="list-style-type: none"> • LOA is expired on 31-12-2023. • Provide Valid ISO Certificate.
30.	M/s MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier#4152-P Submission date:22/02/2023 Fee submitted: 50,000/- Challan No. 34318069748	Legal Manufacturer: M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China. FSC: China Valid till: 03/06/2024	MINDRAY (PRO GRP (GASTRIN RELEASING PEPTIDE) (CLIA) Codes & Sizes: (Packing specifications as per FSC) 2x50tests 2x100tests Class-C Shelf Life: Kit: 12 months	Deferred for the provision of following: <ul style="list-style-type: none"> • Provide embassy attested & valid FSC (China). • Provide valid & notarized CE mark certificate.
31.	M/s MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier#4138-P Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No. 7419503044	Legal Manufacturer: M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China. FSC: China Valid till: 26/09/2023	MINDRAY (Squamous Cell Carcinoma Antigen-SCCA (CLIA)) Codes & Sizes: (Packing specifications as per FSC) C0: 1x1.2ml C1: 1x1.0ml C2: 1x1.0ml Class-C Shelf Life: Kit: 18 months Calibrator: 18 months	Deferred for the provision of following:- <ul style="list-style-type: none"> • Provide embassy attested & valid FSC (china). • Provide valid & notarized CE mark certificate.
32.	M/s MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier#4154-P Submission date: 22/02/2023 Fee submitted:	Legal Manufacturer: M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China. FSC: China Valid till: 03/06/2024	MINDRAY (Carbohydrate Antigen 50) Codes & Sizes: (Packing specifications as per FSC) 2x50tests 2x100tests Class-C Shelf Life: Kit: Not provided Calibrator: 18 months	Deferred for the provision of following:- <ul style="list-style-type: none"> • Provide embassy attested & valid FSC (china). • Provide valid & notarized CE mark certificate. • Stability studies of kit are not provided.

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	50,000/- Challan No. 785233881			
33.	M/s MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier#4140-P Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No. 0863713915	Legal Manufacturer: M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China. FSC: China Valid till: 03/06/2024	MINDRAY (Carbohydrate Antigen242 (CLIA) Kit and Calibrators) Codes & Sizes: (Packing specifications as per FSC) 2x50tests 2x100tests Class-C Shelf Life: Kit: not provided Calibrator: 18 months	Deferred for the provision of following:- <ul style="list-style-type: none">• Provide embassy attested & valid FSC (china).• Provide valid & notarized CE mark certificate.
34.	M/s Moody Global Services Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926 Dossier# 4116- Isb Submission date:03/08/2023 Fee submitted: 50,000/- Challan No. 351169765018	Legal Manufacturer: M/s Hangzhou Realy Tech Co., Ltd, No.2, Building, No. 763, Yuansha Village, Xinjijie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, People's Republic of China Original FSC: China Date of Issue: 05/05/2023 Original FSC: Germany Date of Issue: 20/03/2023	Realy (Malaria p.f Rapid Test Device) Codes & Sizes: K270916D Class-D Shelf Life: 24 months	Deferred for the provision of following:- <ul style="list-style-type: none">• Provide Stability studies of claimed shelf life of 24 months.
35.	M/s Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 4049- KP Submission date:02/08/2023 Fee submitted:	Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland. Original FSC: USA Valid till: 12/10/2024	Essentio MRI Model: L131 (Pulse Generator: Implantable Pacemaker) Codes & Sizes: Model: L131 Class-D Shelf life: 2 years	Deferred for the provision of following:- <ul style="list-style-type: none">• Manufacturing site i.e., Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland is not mentioned on credentials of manufacturer.• LOA is expired on 31-12-2023.• The address of importer mentioned on LOA is <u>Ferozs Laboratories Limited, 197-A the Mall Rawalpindi 42000 Pakistan</u> while on establishment license (Form-4) it is <u>Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK), Pakistan</u>. Justify it.

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	50,000/-PKR Challan# 4307057199			<ul style="list-style-type: none"> • ISO certificates for legal manufacturer (<u>Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</u>) & manufacturing site (<u>Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland</u>) are not submitted. • FQA certificates for legal manufacturer & manufacturing site are not submitted. • DOC for the applied product is not submitted. • EC Design examination certificate for the applied product Essentio MRI Model: L131 is not submitted.
36.	<p>M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120</p> <p>Dossier# 4050-KP</p> <p>Submission date: 02/08/2023</p> <p>Fee submitted: 50,000/-PKR</p> <p>Challan# 471846030515</p>	<p>Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</p> <p>Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland.</p> <p>FSC: USA Valid till: 12/10/2024</p>	<p>Inogen X4 CRT-D (Cardiac Resynchronization Therapy Defibrillator)</p> <p>Models: G146, G148</p> <p>Class-D</p> <p>Shelf life: 2 years</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Manufacturing site i.e., Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland is not mentioned on credentials of manufacturer. • LOA is expired on 31-12-2023. • The address of importer mentioned on LOA is <u>Feroszons Laboratories Limited, 197-A the Mall Rawalpindi 42000 Pakistan</u> while on establishment license (Form-4) it is <u>Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan</u>. Justify it. • ISO certificates for legal manufacturer (<u>Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</u>) & manufacturing site (<u>Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland</u>) are not submitted. • FQA certificates for legal manufacturer & manufacturing site are not submitted. • DOC for the applied product is not submitted.
37.	<p>M/s Feroszons Laboratories Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120</p> <p>Dossier# 4051-</p>	<p>Legal Manufacturer: Boston scientific Corporation 300., Boston Scientific Way, Marlborough, MA 01752 USA</p> <p>Manufacturing Site: Creganna Medical Parkmore West, Galway, Ireland</p>	<p>Zurpaz™ Steerable Sheth Set, Symmetric Model</p> <p>(Cardiovascular device introducer, steerable)</p> <p>Codes & Sizes: M004EPTMC85300</p> <p>Class-D</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Manufacturing site i.e., <u>Creganna Medical Parkmore West, Galway, Ireland</u> is not mentioned on credentials of manufacturer. • LOA is expired on 31-12-2023. • The address of importer mentioned on LOA is <u>Feroszons Laboratories Limited, 197-A the Mall Rawalpindi</u>

Submitted - 01/11/24


	<p>KP</p> <p>Submission date:02/08/2023</p> <p>Fee submitted: 50,000/-PKR</p> <p>Challan# 071951798</p>	<p>FSC: Ireland</p> <p>Issued date: 07/02/2022</p>	<p>Shelf life: 2 years</p>	<p>42000 Pakistan while on establishment license (Form-4) it is Ferozsos <u>Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan.</u> Justify it.</p> <ul style="list-style-type: none"> FQA certificate for M/S Creganna Medical Parkmore West, Galway, Irelandns expired on 15-09-2023 but valid upon submission. EC Design examination certificate is expired on 15-09-2023 but valid upon submission. ISO certificate for legal manufacturer expired on 01-09-2023 but valid upon submission. Provide valid ISO certificate, CE certificate & CE design examination certificate. DOC for the applied product is not submitted. Apply separate case with separate fee of 50,000 PKR for Zurpaz™ Steerable Sheth Set, Asymmetric Model(M004EPTMCA85400)
38.	<p>M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan ELI: 00120</p> <p>Dossier# 4053-KP</p> <p>Submission date:02/08/2023</p> <p>Fee submitted: 50,000/-PKR</p> <p>Challan# 8000517473</p>	<p>Legal Manufacturer: Boston scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA</p> <p>Manufacturing Site: Boston Scientific Limited Ballybrit Business Park, Galway, Ireland</p> <p>FSC: Ireland Date of Issue: 01/12/2022</p>	<p>Acurate neo 2 Transfemoral Delivery System (SYM-DS-010) (Cardiac Valves Transcatheter Implant)</p> <p>Codes & Sizes: (SYM-DS-010)</p> <p>Class-D</p> <p>Shelf life: 12 months</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> Manufacturing site i.e., <i>Boston Scientific Limited Ballybrit Business Park, Galway, Ireland</i> is not mentioned on credentials of manufacturer. LOA is expired on 31-12-2023. The address of importer mentioned on LOA is <u>Ferozsos Laboratories Limited, 197-A the Mall Rawalpindi 42000 Pakistan</u> while on establishment license (Form-4) it is Ferozsos <u>Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan.</u> Justify it. Apply separate case with separate fee of 50,000 PKR for Acurate neo 2 Loading Kit (SYM-AC-010).
39.	<p>M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan ELI: 00120</p> <p>Dossier# 4054-KP</p> <p>Submission date:02/08/2023</p>	<p>Legal Manufacturer: Boston scientific Corporation 4100 Hamline Ave N Saint Paul, MN, USA 55112</p> <p>Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland</p> <p>FSC: USA Date of Issue:</p>	<p>Inogen EL ICD (Implantable cardioverter Defibrillator)</p> <p>Model: D140, D141,D142,D143</p> <p>Class-D</p> <p>Shelf life: 2 years</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> Manufacturing site i.e., <i>Boston Scientific Limited Ballybrit Business Park, Galway, Ireland</i> is not mentioned on credentials of manufacturer. LOA is expired on 31-12-2023. The address of importer mentioned on LOA is <u>Ferozsos Laboratories Limited, 197-A the Mall Rawalpindi 42000 Pakistan</u> while on establishment license (Form-4) it is Ferozsos <u>Laboratories Limited, P.O</u>

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	<p>Fee submitted: 50,000/-PKR</p> <p>Challan# 1471030631</p>	12/10/2024		<p><u>Ferozsons, Amangarh, Nowshera (KPK), Pakistan</u>, Justify it.</p> <ul style="list-style-type: none"> • ISO certificates for legal manufacturer (<u>Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</u>) & manufacturing site (<u>Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland</u>) are not submitted. • FQA certificates for legal manufacturer & manufacturing site are not submitted. • DOC for the applied product is not submitted.
40.	<p>M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120</p> <p>Dossier# 4328-KP</p> <p>Submission date: 02/08/2023</p> <p>Fee submitted: 50,000/-PKR</p> <p>Challan# 6316286338</p>	<p>Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</p> <p>Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland FSC: U.S.A Valid till: 12/10/2024</p>	<p>INOGEN CRT-D (Cardiac Resynchronization Therapy Defibrillator)</p> <p>Models: G140, G141</p> <p>Class-D Shelf Life: 2 years</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Manufacturing site i.e., <u>Boston Scientific Limited Ballybrit Business Park, Galway, Ireland</u> is not mentioned on credentials of manufacturer. • LOA is expired on 31-12-2023. • The address of importer mentioned on LOA is <u>Ferozsons Laboratories Limited, 197-A the Mall Rawalpindi 42000 Pakistan</u> while on establishment license (Form-4) it is <u>Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan</u>, Justify it. • ISO certificates for legal manufacturer (<u>Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</u>) & manufacturing site (<u>Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland</u>) are not submitted. • FQA certificates for legal manufacturer & manufacturing site are not submitted. • DOC for the applied product is not submitted.
41.	<p>M/s Hitec Corporation Office No. 2, 1st Floor, Ali Complex, Plaza NO. 77, Blue Area Fazal-e-Haq Road Islamabad ELI 00355 Dossier# 3713- isb</p>	<p>Legal Manufacturer: M/s Suzhou Beyo Medical Technology Co.,Ltd, 2nd Floor, 5th Building, No. 38 Beiguandu Road, Wuzhong District, Suzhou, P.R. China FSC: China Valid till: 2023/08/20</p>	<p>BEYO MEDICAL (Disposable Double J Ureteral Stent)</p> <p>Codes & Sizes: Not provided.</p> <p>Class:C Shelf Life: 5 years</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Provide original Bank deposit slip as proof of fee submitted. • Photocopied FSC (China) is provided which is expired on 20-08-2023. • Highlight the codes & sizes on FSC for the relevant applied product. • Provide original, valid & embassy attested FSC of country of origin. • Provide original, valid & embassy



	<p>Submission date: 11/01/2023</p> <p>Fee submitted:</p> <p>Challan# not provided.</p>			<p>attested FSC of reference country or CE mark certificate.</p> <ul style="list-style-type: none"> • Provide valid & notarized LOA. • ISO certificate is expired (on 16-10-2022) at the time of submission. • Provide valid & notarized ISO, FQA certificates. • Provide notarized credentials of manufacturer. • Stability studies of claimed shelf i.e., 05 years are not submitted.
42.	<p>M/s A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3588-P Submission date:21/09/2022</p> <p>Fee submitted: 50,000/- Challan# 2698361326</p>	<p>Legal Manufacturer: M/s Acon Laboratories, Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America FSC: China Valid till: 2023/01/17</p>	<p>Acon Mission Ultra Hemoglobin (Hb) Testing Strips (Hemoglobin (Hb) Testing Strips) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Provide original, valid & embassy attested FSC of country of origin (USA). • ISO certificate is expired (on 06-09-2022) at the time of submission. • EC certificate is expired (on 12-09-2022) at the time of submission. • Provide valid & notarized ISO, FQA certificates. • Clarify the brand name as its <u>Acon Mission Ultra Hemoglobin (Hb) Testing Strips</u> on form-7A, while its <u>Mission Ultra Hemoglobin (Hb) Testing Strips</u> on product Labels. • Provide valid DOC of product.
43.	<p>M/s Moody Global Services, Office No. 14, 2nd Floor, Mujajid Plaza Jinnah Avenue, Blue Area Islamabad 44000, Pakistan. ELI:00926 Dossier# 4313-isb Submission date:26/10/2023</p> <p>Fee submitted: 50,000/- Challan# 947938529317</p>	<p>Legal Manufacturer: M/s Shenzhen Lifotronic Technology Co., Ltd, Unit A, 4th Floor, Building 15, Yijing Estate, No. 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC: China Valid till: 14/04/2024 LOA valid till:31-12-2027</p>	<p>Lifotronic (Free Prostate Specific Antigen (Electrochemiluminescence Immunoassay) Sizes: 50T, 2x50T, 100T, 2x100T, 5x100T Class-C Shelf Life: 90 days</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • FSC of reference country/ CE mark certificate is not provided.
44.	<p>M/s Moody Global Services, Office No. 14, 2nd Floor,</p>	<p>Legal Manufacturer: M/s Shenzhen Lifotronic Technology Co., Ltd, Unit A, 4th Floor, Building 15,</p>	<p>Lifotronic (HYPERSENSITIVITYC -Reactive Protein (hs-CRP) Assay kits (Lateral Flow Immunoassay)</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Submit differential fee of 25000/- PKR as fee for class C product is 50,000/- PKR and firm has

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	Mujajid Plaza Jinnah Avenue, Blue Area Islamabad 44000, Pakistan. ELI:00926 Dossier# 4316- isb Submission date: 26/10/2023 Fee submitted: 25,000/- Challan# 6876681318	Yijing Estate, No. 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC: Germany Issued on:22-06-2021 FSC: China Valid till: 03/04/2024 LOA valid till:31-12- 2027	Sizes: 10Tests/kit, 25Tests/kit, 50Tests/kit, 100Tests/kit. Class-C Shelf Life: 10 months	submitted only 25000/- PKR vide Challan# 6876681318.
45.	M/s Malik IOL, Room No. B-14,15,16,17, 2nd Floor, Tehmas Khan Building, Tehkal Payan Univesity Road, Peshawar ELI: 00829 Dossier# 4292- kp Submission date:26/10/2023 Fee submitted: 50,000/- Challan# 32024002	Legal Manufacturer: M/s PT.Rohto Laboratories Indonesia Wisma Barito Pacific Lt.7 Tower B Jl.Letjen S. Parman, kav 62-63, Silipi Palmerah, Jakarta, Barat 11410 Manufacturing site: M/s PT.Rohto Laboratories Indonesia Jl.Raya Cimareme No. 203, Kel. Cimareme, Kec. Ngamprah, Kab. Bandung Barat, Indonesia. Original FSC: Indonesia Date of Issue: 31/08/2021 Valid till:31-08-2023 LOA Valid till:18-07- 2026	Neo Eye ® (Intraocular Lens) Codes & Sizes: RE-03PH/Diameter optik 6.50mm, RE-06F/Diameter optik 6.50mm, RP-11/Diameter optik 5.25mm, RP-12/Diameter optik 5.50mm., RA-25/Diameter optik 6.00mm, Class-C Shelf Life: 05 Years	Deferred for the provision of following: <ul style="list-style-type: none">• FSC Country of origin is expired but valid upon submission. Provide valid FSC.• ISO certificate is expired (on 28-02-2022) at the time of submission of application. Provide notarized ISO certificate.• CE certificate is expired (on 24-04-2023) at the time of submission of application. Provide notarized CE certificate.
46.	M/s Malik IOL, Room No. B-14,15,16,17, 2nd Floor, Tehmas Khan Building, Tehkal Payan Univesity Road, Peshawar ELI: 00829 Dossier# 4293- Kp Submission date:26/10/202 3 Fee submitted: 50,000/- Challan# 50353834468	Legal Manufacturer: M/s PT.Rohto Laboratories Indonesia Wisma Barito Pacific Lt.7 Tower B Jl.Letjen S. Parman, kav 62-63, Silipi Palmerah, Jakarta, Barat 11410 Manufacturing site: M/s PT.Rohto Laboratories Indonesia Jl.Raya Cimareme No. 203, Kel. Cimareme, Kec. Ngamprah, Kab. Bandung Barat, Indonesia. Original FSC: Indonesia Date of Issue: 31/08/2021 LOA Valid till:18-07- 2026	Neo Eye ® (Hydrophobic Lens) Codes & Sizes: RH-72 Class-C Shelf Life: 05 Years	Deferred for the provision of following:- <ul style="list-style-type: none">• FSC Country of origin is expired but valid upon submission. Provide valid FSC.• ISO certificate is expired (on 28-02-2022) at the time of submission of application. Provide notarized ISO certificate.• CE certificate is expired (on 24-04-2023) at the time of submission of application. Provide notarized CE certificate.

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47.	M/s Malik IOL, Room No. B-14,15,16,17, 2nd Floor, Tehmas Khan Building, Tehkal Payan Univesity Road, Peshawar ELI: 00829 Dossier# 4294-kp Submission date: 26/10/2023 Fee submitted: 50,000/- Challan# 69200790	Legal Manufacturer: M/s PT.Rohto Laboratories Indonesia Wisma Barito Pacific Lt.7 Tower B Jl.Letjen S. Parman, kav 62-63, Silipi Palmerah, Jakarta, Barat 11410 Manufacturing site: M/s PT.Rohto Laboratories Indonesia Jl.Raya Cimareme No. 203, Kel. Cimareme, Kcc. Ngamprah, Kab. Bandung Barat, Indonesia. Original FSC: Indonesia Date of Issue: 31/08/2021 LOA Valid till:18-07-2026	Neo Eye ® (Foldable Lens) Codes & Sizes: RF-22L/Diameter 6.00mm Class-C Shelf Life: 05 Years	Deferred for the provision of following:- <ul style="list-style-type: none">FSC Country of origin is expired but valid upon submission. Provide valid FSC.ISO certificate is expired (on 28-02-2022) at the time of submission of application. Provide notarized ISO certificate.CE certificate is expired (on 24-04-2023) at the time of submission of application. Provide notarized CE certificate.
48.	M/s Bone-Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi, 46000 Godown Address: Office 35-, 37. First Floor, Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4377-P Submission date:23/11/2023 Fee submitted: 50,000 Challan# 30721983096	Legal Manufacturer: Tipsan Tibbi Aletler San, Ve Tic, A.S Kemalpaşa Cad.7404/1 Sok. No. 3, Pınarbaşı /İZMİR Türkiye FSC:Türkiye Date of Issue: 07/09/2020 LOA Valid till: 15/04/2026	Modular Head System (Modular Head System) Class-D Shelf Life: N/A	Deferred for the provision of following:- <ul style="list-style-type: none">EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate.EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.
49.	M/s Bone-Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi, 46000 Godown Address: Office 35-, 37. First Floor,	Legal Manufacturer: M/s TIPSAN TIBBI ALETLER SAN, VE TIC, A.S Kemalpaşa Cad.7404/1 Sok. No. 3, Pınarbaşı /İZMİR Türkiye FSC:Türkiye Date of Issue: 20/02/2023 LOA Valid till: 15/04/2026	Prizma hip System (Prizma hip System) Codes & Sizes: Class-D Shelf Life: N/A	Deferred for the provision of following:- <ul style="list-style-type: none">EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate.EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.

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	Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4378-P Submission date:23/11/2023 Fee submitted: 50,000 Challan# 96113581			
50.	M/s Bone- Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi, 46000 Godown Address: Office 35-, 37. First Floor, Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4379-P Submission date:23/11/2023 Fee submitted: 50,000 Challan# 907548804	Legal Manufacturer: M/s TIPSAN TIBBI ALETLE SAN, VE TIC, A.S Kemalpa Cad.7404/1 Sok. No. 3, Pinarbasi /IZMIR Turkiye FSC Original:Turkiye Date of Issue: 07/09/2020 LOA Valid till: 15/04/2026	T-2H Hip Prosthesis System (T-2H Hip Prosthesis System) Class-D Shelf Life: N/A	Deferred for the provision of following:- • EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate. • EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.
51.	M/s Bone- Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi. Godown Address: Office 35-, 37. First Floor, Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4380-P Submission date:23/11/2023 Fee submitted: 50,000 Challan# 86941894156	Legal Manufacturer: M/s TIPSAN TIBBI ALETLE SAN, VE TIC, A.S Kemalpa Cad.7404/1 Sok. No. 3, Pinarbasi /IZMIR Turkiye FSC Original:Turkiye Date of Issue: 07/09/2020 LOA Valid till: 15/04/2026	Acetabular Cup Cemented System (Acetabular Cup Cemented System)) Class-D Shelf Life: N/A	Deferred for the provision of following:- • EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate. • EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.

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52.	<p>M/s Bone-Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi.</p> <p>Godown Address: Office 35-, 37. First Floor, Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4381-P Submission date: 23/11/2023 Fee submitted: 50,000 Challan# 3516570705</p>	<p>Legal Manufacturer: M/s TIPSAN TIBBI ALETLE SAN, VE TIC, A.S Kemalpaşa Cad.7404/1 Sok. No. 3, Pınarbaşı /İZMİR Türkiye FSC Original:Türkiye Date of Issue: 07/09/2020 LOA Valid till: 15/04/2026</p>	<p>(Pressfit Cup Ti+ HA coated Sterile Ceramic Liner PE Liner Starex Screw (Pressfit Cup Ti+ HA coated Sterile Ceramic Liner PE Liner Starex Screw)</p> <p>Class-D Shelf Life: N/A</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate. • EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.
53.	<p>M/s Bone-Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi.</p> <p>Godown Address: Office 35-, 37. First Floor, Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4382-P Submission date:23/11/2023 Fee submitted: 50,000 Challan# 6775086169</p>	<p>Legal Manufacturer: M/s TIPSAN TIBBI ALETLE SAN, VE TIC, A.S Kemalpaşa Cad.7404/1 Sok. No. 3, Pınarbaşı /İZMİR Türkiye FSC Original:Türkiye Date of Issue: 07/09/2020 LOA Valid till: 15/04/2026</p>	<p>Modular Bipolar Cup Uncemented with Instruments set System (Modular Bipolar Cup Uncemented with Instruments Set System)</p> <p>Class-D Shelf Life: N/A</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate. • EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.
54.	<p>M/s Bone-Med, Office # 44, 46, 48, 50 First Floor, Mian Plaza, Chandi Chowk, Rawalpindi, 46000</p> <p>Godown Address: Office 35-, 37.</p>	<p>Legal Manufacturer: M/s TIPSAN TIBBI ALETLE SAN, VE TIC, A.S Kemalpaşa Cad.7404/1 Sok. No. 3, Pınarbaşı /İZMİR Türkiye FSC Original:Türkiye Date of Issue: 07/09/2020 LOA Valid till: 15/04/2026</p>	<p>CTD Modular Straight Stem Cemented, CTPH Modular Straight Stem with Ti+HA coated Uncemented, cement Plug, Stem Centralizer system (CTD Modular Straight Stem Cemented, CTPH Modular Straight Stem with Ti+HA coated</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • EC certificate is expired (on 23-10-2023) at the time of submission. Provide notarized & valid EC certificate. • EC design examination certificate for the applied product is not submitted. Provide notarized & valid EC design examination certificate.

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	First Floor, Mian Plaza, Chandi Chowk, Rawalpindi ELI: 01157 Dossier#4383-P Submission date:23/11/2023 Fee submitted: 50,000 Challan# 95659075		Uncemented, cement Plug, Stem Centralizer system) Class-D Shelf Life: N/A	
55.	M/s Asto Life Science (Pvt) Ltd., Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore ELI: 00103 Dossier# 407-P Submission date:16/05/2023 Fee submitted: 5,000/- Challan# 15489881852	Legal Manufacturer: Certest Biotec, S.L Poligono Industrial Rio Callego II, calle J, n01 p.O, 50840 San Mateo de Gallego, Zaragoza, Spain FSC: Spain Date of Issue: 29/09/2022	CerTest H. pylori (Card kit x 20 tests + PC) (H.Pylori Test Kit) Codes & Sizes: N/A Class-A Shelf Life: 24 months	Deferred for the provision of following:- <ul style="list-style-type: none"> • LOA is expired on 11-04-2023 at the time of submission. Provide notarized & valid LOA. • Provide notarized ISO certificate. • Provide notarized FQA certificate. • Provide stability studies of claimed shelf life. • Provide DOC as per European format & mention the medical device class on it.
56.	Asto Life Science (Pvt) Ltd., Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore ELI: 00103 Dossier# 408-P Submission date:16/05/2023 Fee submitted: 5,000/- Challan# 93070487	Legal Manufacturer: Certest Biotec, S.L Poligono Industrial Rio Gallego II, calle J, n01 p.O, 50840 San Mateo de Gallego, Zaragoza, Spain FSC: Spain Date of Issue: 29/09/2022	CerTest Adenovirus (Card kit x 20 tests + PC) (Adenovirus Test Kits) Codes & Sizes: N/A Class-A Shelf Life: 24 months	Deferred for the provision of following:- <ul style="list-style-type: none"> • LOA is expired on 11-04-2023 at the time of submission. Provide notarized & valid LOA. • Provide notarized ISO certificate. • Provide notarized FQA certificate. • Provide stability studies of claimed shelf life. • Provide DOC as per European format & mention the medical device class on it.
57.	M/s Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg- IV, Lahore ELI: 00554 3140-P 04-07-2022	Legal Manufacturer: Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH, 45237, U.S.A FSC: U.S.A Valid till:23/03/2023	OptiOne Single-Head Contrast Delivery system (Power Injector with Pedestal) Class-C Shelf Life: 7 years Code: S8474	Deferred for the clarification as the LOA is between Gubert Asia Pacific Limited, Hong Kong and Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore whereas the Legal manufacturer is Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH 45237, U.S.A. Furthermore, provide :- <ul style="list-style-type: none"> • Updated and original FSC • Updated ISO 13485 certificate.
58.	M/s Medical Equipment &	Legal Manufacturer: Liebel-Flarsheim	Illumena Neo Contrast Delivery System	Deferred for the clarification as the LOA is between Gubert Asia Pacific Limited,

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	System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore ELI: 00554 3141-P 04-07-2022	Company, LLC 2111 E. Galbraith Rd Cincinnati, OH, 45237, U.S.A FSC: U.S.A Valid till:23/03/2023	(Injector System with Pedestal) Class-C Shelf Life: 7 years Code: 7216	Hong Kong and Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore whereas the Legal manufacturer is Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH 45237, U.S.A. Furthermore, provide :- <ul style="list-style-type: none"> Updated and original FSC Updated ISO 13485 certificate.
59.	M/s Medical Devices Specialty, Office # 1-2, First Floor, Al-Riaz Plaza, Bank Road Saddar, Rawalpindi. ELI: --00919 4217-P 09-10-2023	Legal Manufacturer: M/s Eye Bright, Medical Technology (Beijing) Co., Ltd No. 9 Xingchang Road, Changping Science Park, Changping District, Beijing 102200, P.R China FSC Netherland Validity 19-01-2024	EDOF (Extend Depth of Focus) Hydrophobic Preloaded Aspheric IOL Class- C Shelf Life: 5 years Codes: AE2UL22 AE2UL24 AE2UL28	Deferred for provision of following:- <ul style="list-style-type: none"> Valid LOA Valid ISO 13485.
60.	M/s Medical Devices Specialty, Office # 1-2, First Floor, Al-Riaz Plaza, Bank Road Saddar, Rawalpindi. ELI: --00919 4218-P 09-10-2023	Legal Manufacturer: M/s Eye Bright, Medical Technology (Beijing) Co., Ltd No. 9 Xingchang Road, Changping Science Park, Changping District, Beijing 102200, P.R China FSC Netherland Validity 19-01-2024	Prosert AQ (AQBXL) Hydrophobic Preloaded Yellow Chromophore Aspheric Lens (IOL) Class-C Shelf Life: 5 years Codes: AQBXL22 AQBXL24 AQBXL28	Deferred for provision of following:- <ul style="list-style-type: none"> Valid LOA Valid ISO 13485.
61.	M/s Medical Devices Specialty, Office # 1-2, First Floor, Al-Riaz Plaza, Bank Road Saddar, Rawalpindi. ELI: --00919 4219-P 09-10-2023	Legal Manufacturer: M/s Eye Bright, Medical Technology (Beijing) Co., Ltd No. 9 Xingchang Road, Changping Science Park, Changping District, Beijing 102200, P.R China FSC Netherland Validity 19-01-2024	Prosert (AIUL) Hydrophobic Preloaded Clear Aspheric IOL Class-C Shelf Life: 5 years Codes: AIUL22 AIUL24 AIUL28	Deferred for provision of following:- <ul style="list-style-type: none"> Valid LOA Valid ISO 13485.
62.	M/s Hospicare Systems 9 th Floor, Emarah Suites, Plot 8-B Block A SMCHS Shahrah-e-Faisal Karachi,	Legal Manufacturer: Gentherm Medical LLC, 12011 MOSTELLER RD. Cincinnati, OH USA 45241. FSC US FDA validity	GELLI-ROLL (Reusable Hypo/hyperthermia Blankets) Class-C Shelf life: 2 years	Deferred for the provision of following: <ul style="list-style-type: none"> Updated LOA, FSC, ISO 13485 and FQA certificates.

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	75350. ELI-00274 3761 26-09-2022 Duplicate Dossier	20-12-2023 FSC Netherland Validity 01-12-2023	Codes: 82197 82198 82199	
63.	Hospicare Systems 9 th Floor, Emarah Suites, Plot 8-B Block A SMCHS Shahrah-e-Faisal Karachi, 75350. ELI-00274 3763 26-09-2022 Duplicate Dossier	Legal Manufacturer: Gentherm Medical LLC, 12011 MOSTELLER RD. Cincinnati, OH USA 45241. FSC US FDA validity 20-12-2023 FSC Netherland Validity 01-12-2023	Plastipad (Reusable Hypo/hyperthermia Blankets) Class-C Shelf life: 1 years Codes: 82184,50103,82196, 82192, 50111,82193 82194	Deferred for the provision of following: • Updated LOA, FSC, ISO 13485 and FQA certificates.
64.	Hospicare Systems 9 th Floor, Emarah Suites, Plot 8-B Block A SMCHS Shahrah-e-Faisal Karachi, 75350. ELI-00274 3761 26-09-2022 Duplicate Dossier	Legal Manufacturer: Gentherm Medical LLC, 12011 MOSTELLER RD. Cincinnati, OH USA 45241. FSC US FDA validity 20-12-2023 FSC Netherland Validity 01-12-2023	FilteredFlo (Air Hyper-Hypothermia Blanket) Class-C Shelf life: Disposable Single Patient Use Codes as per FSC	Deferred for the provision of following: • Updated LOA, FSC, ISO 13485 and FQA certificates. • Multiple (9 types including Warming tube) types of Blankets applied in single application, give your priority for subject case and apply separately for others.
65.	M/s Physiomed Pvt Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI: 00199 4341-P 26-10-2023	Legal Manufacturer: M/s St Jude Medical Ltd, Irvine Biomedical, Inc. a St. Jude Medical Company 2375 Morse Avenue Irvine, CA 2614 USA Manufacturing Site: M/s St. Jude Medical Ltd Edificio # 44, Calle O, Ave.2, Zone Franca Coyol,El Coyol Alajuela Costa Rica Original FSC: USA Valid till: 16/01/2025	ViewFlex™ Extra ICE Catheter (Intracardiac Imaging Catheter) Class-D Shelf Life: 1 year Code: D087031	Deferred for the provision of following: • Updated LOA, and FQA certificate.
66.	Intiaz Brothers, Suite. No. 7B, 2nd Floor, Abrar Business Center, 25-Main Wahdat Road, Lahore.	Legal Manufacturer: M/s Royal Fornia Medical Equipment Co., Ltd, No. 18, Kejiyi Road, Hi-Tech Innovation Coast, Tangjia Bay, Zhuhai, Guangdong, China.	Fornia Disposable Central Venous catheter Kit (Disposable Central Venous Catheter Kit, Single Lumen) Class-D	Deferred for the provision of following: • Design examination certificate and apply separately for other two types.

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	ELI: 00133 4291-P 26-10-2023	Original FSC: China Valid till: 23/09/2024	Shelf Life: 03 Years Codes & Sizes: As per FSC	
67.	Trowmedic International, Building No.117, sagian, T4, Opposite Sanda stop Band Road Lahore ELI: 00069 4348-P 08-11-2023	Legal Manufacturer: Fitone Latex Products Co., Ltd No. 5 Huitong Road, Lingbei Industrial Zone, Suixi, Zhanjiang, Guangdong China FSC: China Valid till: 25/04/2021	Confidence Male Condoms (Natural Rubber Latex Male condoms) Class-C Shelf Life: As per stability study. Codes & Sizes: As per FSC	Deferred for the clarification since the manufacturer M/s Fitone Latex prouducts co., Guangdong has issued the termination of agency agreement to M/s Trowmedic, Lahore ELI No.00069. M/s Fitone Latex prouducts co., Guangdong. M/s Fitone Latex prouducts co., Guangdong has issued the new agreement with CSM Pakistan (Guarantee) Ltd, Plot no. C-21, ground floor, sector 31-A, Mehran Extension, Korangi industrial area, Karachi.
68.	M/s Med Lab Services Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 1882-P 06-11-2020	Legal Manufacturer: M/s VIRCELL, S.L, Parque Tecnologico de la Salud, Avicena 8, 18016 Granada (Spain) and Poligono Industrial Dos de Octubre, Plaza Dominguez Ortiz 1, 18320 Santa Fe, Granada, Spain. FSC: Spain Date of issue 04.01.2018	Cytomegalovirus ELISA IgG kit (Cytomegalovirus Elisa IgG) Class-C Shelf Life: 21 months Code G1004	Deferred for the provision of following:- • Valid LOA, FSC, ISO 13485 and FQA certificates.
69.	M/s S.J Traders, Office # 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi ELI: 00531 4400-P 06-12-2023	Legal Manufacturer: M/S Fiab, Fiab Spa-Sede Legale: Via P. Costoli, 4-50039 Vicchio-Firenze, Italy FSC Original: Italy Date Of Issue: 15/05/2023	SPIKE ULTRA LC (Leads for temporary cardiac pacing) Class-D Shelf Life: 2 years Codes & Sizes: As per FSC	Deferred for the provision of following:- • Updated and notarized FQA certificate. • Credentials as per format approved in 3 rd meeting of MDB. • Stability studies, manufacturing details and QC tests protocols • The firm applied in Single grouping criteria whereas the application submitted has multiple models, clarification is required. • Labels or brochures • MRP of the device. • Declaration of Conformity, to be printed on manufacturers letter head duly filled and signed by responsible person. • Apply separately for other models.
70.	M/s S.J Traders, Office # 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi ELI: 00531 4401-P	Legal Manufacturer: M/S Fiab, Fiab Spa-Sede Legale: Via P. Costoli, 4-50039 Vicchio-Firenze, Italy FSC Original: Italy Date Of Issue: 15/05/2023	Introducer Sets (Hemostasis valve percutaneous introducer set) Class-C Shelf Life: 2 years	Deferred for the provision of following:- • Updated and notarized FQA certificate. • Credentials as per format approved in 3 rd meeting of MDB. • Stability studies, manufacturing details and QC tests protocols • The firm applied in Single grouping

Handwritten signature: M/s S.J Traders, Office # 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi

	06-12-2023		Codes & Sizes: As per FSC	<p>criteria whereas the application submitted has multiple models, clarification is required.</p> <ul style="list-style-type: none"> • Labels or brochures • MRP of the device. • Declaration of Conformity, to be printed on manufacturers letter head duly filled and signed by responsible person. • Apply separately for other models.
71.	M/s Total Technologies Pvt. Ltd, 696 – J-2, M.A. Johar Town, Lahore, Pakistan License No.: ELI-00129 4455-P 07-12-2023	Legal Manufacturer: Löwenstein Medical SE & Co. KG Arzbacher Strabe.80 56130 Bad Ems/ Germany Steinbech, Germany FSC: Germany Valid till08-01-2024	Leoni plus (Ventilator) Class-C Service Life: 8 years Model: Leoni plus 0217001 (DoC)	Deferred for the provision of following:- <ul style="list-style-type: none"> • The agreement for the subject device between the importer and the legal manufacturer. • Apply separately for the other model • Fee for the subject device is submitted on 05-12-2019, clarification is required.
72.	M/s Total Technologies Pvt. Ltd, 696 – J-2, M.A. Johar Town, Lahore, Pakistan License No.: ELI-00129 4454-P 07-12-2023	Legal Manufacturer: Löwenstein Medical SE & Co. KG Arzbacher Strabe.80 56130 Bad Ems/ Germany Steinbech, Germany FSC: Germany Valid till08-01-2024	Leon plus (Anesthesia workstation) Class-C Service Life: 10 years Model: Leon plus 0200010	Deferred for the provision of following:- <ul style="list-style-type: none"> • The agreement for the subject device between the importer and the legal manufacturer. • Apply separately for the other model • Fee for the subject device is submitted on 05-12-2019, while application is submitted on 07/12/2023 clarification is required.
73.	M/s Total Technologies Pvt. Ltd, 696 – J-2, M.A. Johar Town, Lahore, Pakistan License No.: ELI-00129 4453-P 07-12-2023	Legal Manufacturer: Löwenstein Medical SE & Co. KG Arzbacher Strabe.80 56130 Bad Ems/ Germany Steinbech, Germany FSC: Germany Valid till08-01-2024	Lifetherm 2000 (Baby warming Bed) Class-C Service Life: 8 years Model: Lifetherm 2000 0215500hul2000200010	Deferred for the provision of following:- <ul style="list-style-type: none"> • The agreement for the subject device between the importer and the legal manufacturer. • Apply separately for the other model • Fee for the subject device is submitted on 05-12-2019, clarification is required.
74.	M/s The Cure, Suite No 06, 1st Floor, Capri Center, Firdous Market, Gulberg III, Lahore, Pakistan ELI: 00567 4464-P	Legal Manufacturer: M/s Zhejiang Barty Medical Technology Co., Ltd. Address: Room 101, 201, 301, Building 26, Yin Hai Technology Innovation Center, Xiasha Street, Qiantang District, 310018 Hangzhou City,	ULTRA WANTY HP PTA Balloon Catheter (HP PTA Balloon Catheter) Class-B Shelf life 2 years Codes & Sizes: As per FSC	Deferred for the provision of following:- <ul style="list-style-type: none"> • Credentials of manufacturer abroad • Address of the manufacturer on LOA and FSC is different from the address mentioned on ISO 13485 and FQA/ CE certificate, clarification is required. • The firm applied in Class-B whereas the subject device is registered in Class-C so differential fee of Rs.

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	21-12-2023	Zhejiang Province, China. FSC Original: China Valid till: 2024/02/27		25000/- to be submitted. • FSC of any reference country.
75.	M/s The Cure, Suite No 06, 1st Floor, Capri Center, Firdous Market, Gulberg III, Lahore, Pakistan ELI: 00567 4465-P 21-12-2023	Legal Manufacturer: M/s Zhejiang Barty Medical Technology Co., Ltd. Address: Room 101, 201, 301, Building 26, Yin Hai Technology Innovation Center, Xiasha Street, Qiantang District, 310018 Hangzhou City, Zhejiang Province, China. FSC Original: China Valid till: 2024/02/27 (Original Documents)	LEETY™ PTCA Balloon Catheter (PTCA Balloon Catheter) Class-D Shelf life: 2 years Codes & Sizes: As per FSC	Deferred for the provision of following: • Credentials of manufacturer abroad • Address of the manufacturer on LOA and FSC is different from the address mentioned on ISO 13485 and FQA/ CE certificate, clarification is required. • The firm applied in Class-B whereas the subject device is registered in Class-C so differential fee of Rs. 25000/- to be submitted. • FSC of any reference country.
76.	M/s The Cure Suite No 06, 1st Floor, Capri Center, Firdous Market, Gulberg III, Lahore, Pakistan ELI: 00567 4466-P 21-12-2023	Legal Manufacturer: M/s Zhejiang Barty Medical Technology Co., Ltd. Address: Room 101, 201, 301, Building 26, Yin Hai Technology Innovation Center, Xiasha Street, Qiantang District, 310018 Hangzhou City, Zhejiang Province, China. FSC Original: China Valid till: 2024/02/27	WANTY™ PTA Balloon Catheter (PTA Balloon Catheter) Class-B Shelf life: 2 Year Codes & Sizes: As per FSC	Deferred for the provision of following: • Credentials of manufacturer abroad • Address of the manufacturer on LOA and FSC is different from the address mentioned on ISO 13485 and FQA/ CE certificate, clarification is required. • The firm applied in Class-B whereas the subject device is registered in Class-C so differential fee of Rs. 25000/- to be submitted. • FSC of any reference country.
77.	M/s The Cure Suite No 06, 1st Floor, Capri Center, Firdous Market, Gulberg III, Lahore, Pakistan ELI: 00567 4467-P 21-12-2023	Legal Manufacturer: M/s Zhejiang Barty Medical Technology Co., Ltd. Address: Room 101, 201, 301, Building 26, Yin Hai Technology Innovation Center, Xiasha Street, Qiantang District, 310018 Hangzhou City, Zhejiang Province, China. FSC Original: China Valid till: 2024/02/27	Ultra LEETY™ HP PTCA Balloon Catheter (PTCA Balloon Catheter) Class-D Shelf life: 3 Years Codes & Sizes: As per FSC	Deferred for the provision of following:- • Credentials of manufacturer abroad • Address of the manufacturer on LOA and FSC is different from the address mentioned on ISO 13485 and FQA/ CE certificate, clarification is required. • The firm applied in Class-B whereas the subject device is registered in Class-C so differential fee of Rs. 25000/- to be submitted. • Design examination certificate • FSC of any reference country.
78.	M/s Ontech Corporation B-154 Block 13-D/2 Gulshan -e-	M.S. Electro Medical Systems S.A. Address: Ch. de la Vuarpillière 31 CH-1260 Nyon -	SWISS LITHOCLAST MASTER AND ACCESSORIES Class C	Deferred for provision of original valid notorised LOA & valid copies of ISO 13485 & Service Life/ Stability data.

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	Iqbal, Karachi, Pakistan. (ELI-00289) Submission date 13-07-2022	Switzerland FSC: Switzerland Valid Till: 03-06-2025	Shelf life:	
79.	M/s Ontech Corporation B-154 Block 13-D/2 Gulshan -e- Iqbal, Karachi, Pakistan. (ELI-00289) Submission date 04-06-2022	PLASTI-MED Plastik Medikal Ürünleri San. Ve Tic. Ltd. Şti. Address: Deri OSB Mah. Yan Sanayi Cad. No:13 Tuzla/ISTANBUL, TURKIYE. FSC: Turkey Valid Till: 21-08-2023	PLASTI-MED URETERAL STENTS SETS Class C Shelf life:	Deferred for provision of original notorised LOA, CE, ISO 13485 & Service Life/ Stability data. Separate applications for all types.
80.	M/s Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061)	Bovie Medical Corporation 5115 Ulmerton Road Clearwater, Florida 33760 FSC: USFDA valid till 18-04-25	Bovie High Frequency Electrosurgical Generator IDS-310 Class C Service Life: 7 years	Deferred for provision of ISO 13485 for same manufacturer.
81.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-2022)	ADVANCED QUALITY ONE STEP HBsAg TEST / DIAGNOSTIC KIT FOR HEPATITIS B VIRUS SURFACE ANTIGEN (Colloidal Gold) CAT. NO. ITP01003, Class – D Shelf Life = 24 Months The Kit must be stored at 2-30 °C.	Deferred for the provision of following documents: • FSC of any RRA/ CE Certificate
82.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-2022)	ADVANCE QUALITY ONE STEP ANTI TP (Treponema Pallidum / Syphilis) TEST / DIAGNOSTIC KIT FOR ANTIBODY TO TREPONEMA P ALLIDUM (Colloidal Gold) CAT. NO. ITP03004. Class – D Shelf Life = 24 Months The Kit must be stored at 2-30 °C.	Deferred for the provision of following documents:- • FSC of any RRA/ CE Certificate

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83.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi - 75400, PAKISTAN Lic. No.ELI-00010	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-2022)	ADVANCE QUALITY ONE STEP MALARIA (p.f / p.v) TRI-LINE TEST CAT. NO. ITP11003 Class - D Shelf Life = 24 Months The Kit must be stored at 2-40 °C.	Deferred for the provision of following documents:- • FSC of any RRA/ CE Certificate
84.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi - 75400, PAKISTAN Lic. No.ELI-00010	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-2022)	ADVANCED DIAGNOSTIC KIT FOR HEPATITIS B VIRUS SUFRACE ANTIGEN (ELISA) - CAT. NO. ITP21001. Class - D Shelf Life = 12 Months The Kit must be stored at 2-8 °C.	Deferred for the provision of following documents:- • FSC of any RRA/ CE Certificate
85.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi - 75400, PAKISTAN Lic. No.ELI-00010	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-2022)	ADVANCED DIAGNOSTIC KIT FOR ANTIBODY TO HEPATITIS C VIRUS (ELISA) - CAT. NO. ITP23001. Class - D Shelf Life = 12 Months The Kit must be stored at 2-8 °C.	Deferred for the provision of following documents:- • FSC of any RRA/ CE Certificate
86.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi - 75400, PAKISTAN Lic. No.ELI-00010	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-2022)	ADVANCED QUALITY RAPID ANTI HCV TEST / DIAGNOSTIC KIT FOR ANTIBODY TO HEPATITIS C VIRUS (Colloidal Gold) CAT. NO. ITP01102. Class - D Shelf Life =24 Months The Kit must be stored at 2-30 °C.	Deferred for the provision of following documents. • FSC with relevant CAT No. required
87.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi - 75400, PAKISTAN	InTec PRODUCTS, INC., 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China FSC Valid Till (25-10-	ADVANCED QUALITY RAPID ANTI HIV (1&2) TEST / DIAGNOSTIC KIT FOR ANTIBODY TO HUMAN IMMUNODEFICIENCY VIRUS (Colloidal Gold)	Deferred for the provision of following documents. • FSC with relevant CAT No. required

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	Lic. No.ELI-00010	2022)	CAT. NO. ITP02002. Class – D Shelf Life =12 Months The Kit must be stored at 2-30 °C.	
88.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer: Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA (Embassy Attested CFG USA Validity: 01.08. 2024) LOA issued on 28.10.2022	Vysis FISH Pretreatment Reagent kit 02J03-032 Shelf Life: Not Applicable Class: C Rs.50,000/-	Deferred for clarification and provision of DOC, label and stability studies.
89.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. FSC: UK issue date 16.08.2022 valid till 19-08-2027 (embassy attested Submitted in Optilite® Freelite® Kappa Free Kit)	Optilite® Freelite® Lambda Free Kit Class C Shelf Life: 18 months Code:- LK018.OPT Date of Submission: 31-05-2023 Fee submitted: Rs. 50,000/- Storage temperature: Store at temperature 2-8°C	Deferred for submission of valid and notarsied LOA and FQA or clarify?
90.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. FSC: UK issue date 16.08.2022 valid till 19-08-2027 (embassy attested Submitted	Optilite® Freelite® Kappa Free Kit Class C Shelf Life: 18 months Code:- LK016.OPT Date of Submission: 31-05-2023 Fee submitted: Rs. 50,000/- Storage temperature: Store at temperature 2-8°C	Deferred for submission of valid and notarsied LOA and FQA or clarify?
91.	Muller & Phipps Pakistan (Pvt) Limited Uzma Court, Main Clifton Road, Karachi Date of submission:- 28-08-2023	Legal Manufacturer: Unomedical a/s CVR No. 64153315 Aaholmvej 1-3, Osted 4320 Lejre, Denmark Physical Manufacturer: Unomedical Devices S.A. de C.V. Avenida Fomento Industrial Lote 9, M3 Parque Industrial del Norte	Neria Steel (Infusion set) Class-C Shelf Life:- 05 years Fee Submission: Rs. 50,000/- Code & Size: Neria Steel G27/ G29 Needle Storage Conditions: Store in a dry place at room temperature	Deferred for clarification of the following. <ul style="list-style-type: none">Clarify the Legal manufacturer and Physical manufacturer and revise Form 7A.Calrify the name of the product applied is neria steel while on FSC it is Neria only.Provide notarsied and valid LOA

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		Reynosa, Tamaulipas, C.P. Mexico C.P. 88736 Legalized & Notarized FSC from Denmark, Valid till 24-05-2024		
92.	M/s Biologic Medical Systems (BMS) 166-E, Block No. 3, Annex B, Off Khalid BinWaleed Road P.E.C.H.S Karachi ELI: 000346	Legal Manufacturer HUNTLEIGH HEALTHCARE LTD Diagnostic products Division 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom FSC embassy attested: UK DATE OF ISSUE: 28.01.2019 (Master Files)	HUNTLEIGH FETAL DOPPLER SR2- CLASS-B Shelf Life: N/A	Deferred for submission of the following:- • The name of the product in the FSC is not aligned with the name applied Form 7A, provide or clarify. SONICAID in the FSC CLARIFY • Submit valid ISO 13485, FQA/CE certificaite and valid and notarsied LOA. • Submit EPSP, DOC and manufacturing and testing method. • The firm has not provided service life, clarify.
93.	M/s Biologic Medical Systems (BMS) 166-E, Block No. 3, Annex B, Off Khalid BinWaleed Road P.E.C.H.S Karachi ELI: 000346	Legal Manufacturer HUNTLEIGH HEALTHCARE LTD Diagnostic products Division 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom FSC: UK DATE OF ISSUE: 28.01.2019	HUNTLEIGH VASCULAR DOPPLER Model: DMX-DMXR Class-B Shelf Life: N/A	Deferred for submission of the following:- • The name of the product in the FSC is not aligned with the name applied Form 7A. However, code is the same clarify. Dopplex in the FSC • Submit valid ISO 13485, FQA/CE certificaite and valid and notarsied LOA. • Submit EPSP, DOC and manufacturing and testing method. • The firm has not provided service life, clarify
94.	M/s Biologic Medical Systems (BMS) 166-E, Block No. 3, Annex B, Off Khalid BinWaleed Road P.E.C.H.S Karachi ELI: 000346	Legal Manufacturer HUNTLEIGH HEALTHCARE LTD Diagnostic products Division 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom FSC: UK DATE OF ISSUE: 28.01.2019	HUNTLEIGH Sonicaid team 3 Antepartum and intrapartum Battery FETAL Monitor Model: TEAM3A- TEAM31 Class-C Shelf life: N/A	Deferred for submission of the following:- • Clarification for the brand name and system is required since in FSC only Sonicaid written, clarify the brand name and revise Form7A. • Submit valid ISO 13485, FQA/CE certificaite and valid and notarsied LOA. • Submit EPSP, DOC and manufacturing and testing method. • The firm has not provided service life, clarify
95.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium	Jiangsu Qianjing Medical Equipment Co., Ltd, China Address: No.6	DISPOSABLE ENDOSCOPIC STAPLER AND RELOADS	Deferred for clarification of the System /family under the MDR 2017 and submit embassy attested /Apostille FSC of all the codes of the product applied. • The product is from non-reference

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	Road, Karachi (ELI-00029) Date of submission. 02-06-2022	Fengming Road, Wujin Hi-tech Industrial Development Zone, Wujin District, Changzhou, Jiangsu, China Embassy attested expired FSC: China Valid 11.05.2022 Apostille FSC is valid Till: 20.09.2025.	Class C Shelf Life: 3 years Fees Rs. 50,000/- challan no. 53009877	country and the firm has submitted expired CE certificate. <ul style="list-style-type: none"> • Provide valid and notarsied CE certificate or FSC opf refrence country. • The firm has also submitted two FSC of China, one is already expired (embassy attested) and the other is valid and Apostille.Howvver some codes of the products not clear. Therefore, clarify. • Submit complete stability study.
96.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi (ELI-00029) Date of submission. 02-06-2022	Jiangsu Qianjing Medical Equipment Co., Ltd. China Address: No.6 Fengming Road, Wujin Hi-tech Industrial Development Zone, Wujin District, Changzhou, Jiangsu, China Embassy attested expired FSC: China Valid 11.05.2022 Without embassy attestation FSC is valid Till: 20.09.2025	DISPOSABLE LINEAR CUTTER STAPLERS AND RELOADS Class C Shelf life: 3 years Fees Rs. 50,000/- Challan no. 38371084	Deferred for clarifaication of the System /family under the MDR 2017 and submit embassy attested FSC of all the sizes of the product applied. Or clarify. <ul style="list-style-type: none"> • The product is from non-reference country and the firm has submitted expired CE certificate. • Provide valid and notarsied CE certificate or FSC opf refrence country. • The firm has also submitted two FSC of China, one is already expired (embassy attested) and the other is valid but not embassy attested and is only notarized. • Submit embassy attested valid FSC of China • Submit complete stability study.
97.	M/s AMB HK Enterprises (PvT) Ltd, 2nd Floor Plaza 60, Commercia I Block-K, Phase-1, DHA, Lahore ELI: 00863 Dossier# 3675-P Submission date: 14/02/2023	Legal Manufacturer: M/s Jiangxi Fenglin Medical Applincance Co., Ltd,Fulin Road, Fuzhou Ciity , Jiangxi Province, China FSC: CHINA Valid till: 29/07/2025	SURE-GUARD IV CANNULA (With injection valve) Class-B Shelf Life: 03 years Storage Temperature: +5 to +25-c	Deferred for final opportunity for the provision of following:- <ul style="list-style-type: none"> • Embassy attested valid FSC is still not submitted. • The firm applied IV cannulas of following type in single application: <ul style="list-style-type: none"> • IV Cannula Pen type • IV Cannula with wings & injection port • IV Cannula with wings without injection port. • Apply separate application with separate fee of 25,000/- PKR for each type of IV cannula.
98.	M/s Ahmad Care International, 2nd Floor, 7 Shahrach-eTajbagh, Main Market, Phase 1, Tajbagh Housing	Legal Manufacaturer: M/s Shenzhen Antmed Co., Ltd, 18 Jinhui Avenue, Pingshan New District, Shenzhen 518122 FSC: China Valid till: 13.03.2022	ANTMED (Contrast Media Injectors) Codes & Sizes: As per FSC. Class-C Shelf Life: 10-years	Deferred for final opportunity for the provision of following:- <ul style="list-style-type: none"> • Photocopied CE certificate (Valid till 26-05-2024) is provided. Provide original notarized CE certificate. • Provide valid FSC (China).

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99.	M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018	ASO Latex (Slide Agglutination Serology Test Kit) Coes & sizes: As per FSC 1200101 (50 Tests), 1200102 (100 Tests) , 1200105 (200 Tests) Class-C Shelf Life: 30 months	Deferred for final opportunity for the provision of clarification since another application is submitted by M/s Perfect sciences, Rawalpindi who claimed that M/s Spinreact, Spain has terminated the agreement between M/s Reaction Scientific and Spinreact, Spain.
100.	M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018	Spinreact RF Latex (kit) [Slide Agglutination Serology Test Kit] Codes: 1200201 (50 test) 1200202 (100 test) 1200205 (200 test) Class C Shelf Life: 30 months	Deferred for final opportunity for the provision of clarification since another application is submitted by M/s Perfect sciences, Rawalpindi who claimed that M/s Spinreact, Spain has terminated the agreement between M/s Reaction Scientific and Spinreact, Spain.
101.	M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018	Spinreact RPR Carbon (kit) (Slide Agglutination Serology Test Kit) Code: 1200402 (500 tests) Class C Shelf Life: 30 months	Deferred for final opportunity for the provision of clarification since another application is submitted by M/s Perfect sciences, Rawalpindi who claimed that M/s Spinreact, Spain has terminated the agreement between M/s Reaction Scientific and Spinreact, Spain.
102.	M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018	Spinreact CRP Latex (kit) [Slide Agglutination Serology Test Kit] Code: 1200301 (50 tests) 1200302 (100 tests) 1200305 (200 tests) Class C Shelf Life: 30 months	Deferred for final opportunity for the provision of clarification since another application is submitted by M/s Perfect sciences, Rawalpindi who claimed that M/s Spinreact, Spain has terminated the agreement between M/s Reaction Scientific and Spinreact, Spain.
103.	M/s Jawad Traders, PS Tower City Mall Godown Road Near Govt. Commerce College Peshawar, KPK, Pakistan ELI: 00532 Dossier# 3921-KP Submission date:08/05/2023 Fee submitted: 25,000/-	Legal Manufacturer: M/s Beijing Fert Technology Co., Ltd, Room 4196, Building 1, Shixingdong Jie, Badachu High Scientific and Technologic Garden,, Shijingshan District, Beijing China Original FSC: China Valid till: 2024/01/22	Fert (Sterile IV Catheter) Codes & Sizes: as per FSC Y Model Class-B Shelf Life: 3 years	Deferred with final opportunity for the provision of following:- Notarized ISO & CE mark certificates are submitted but address for legal manufacturer (i.e., M/s Beijing Fert Technology Co., Ltd, 1 st and 2 nd floors of building 3, building 4, courtyard 23, panlong west Road, Mafang town, Pinggu district, 101204 Beijing P.R. China) mentioned on them are different from the address of legal manufacturer as on form-7A & LOA i.e., (M/s Beijing Fert Technology Co., Ltd, Room 4196, Building 1, Shixingdong Jie, Badachu High Scientific and Technologic

m/s Jawad Traders
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	Challan No. 891441409			Garden,, Shijingshan District, Beijing China). Clarification is required.
104.	M/s Jawad Traders, PS Tower City Mall Godown Road Near Govt. Commerce College Peshawar, KPK, Pakistan ELI: 00532 Dossier# 3923-KP Submission date:08/05/2023 Fee submitted: 25,000/- Challan No. 437720164356	Legal Manufacturer: M/s Beijing Fert Technology Co., Ltd, Room 4196, Building 1, Shixingdong Jie, Badachu High Scientific and Technologic Garden,, Shijingshan District, Beijing China FSC: China Valid till: 2024/01/22	Fert (Sterile Safety IV Catheter) Codes & Sizes: As per FSC Y Model single port. Class-B Shelf Life: 3 years	Deferred with final opportunity for the provision of following:- Notarized ISO & CE mark certificates are submitted but address for legal manufacturer (i.e., M/s Beijing Fert Technology Co., Ltd, 1 st and 2 nd floors of building 3, building 4, courtyard 23, panlong west Road, Mafang town, Pinggu district, 101204 Beijing P.R. China) mentioned on them are different from the address of legal manufacturer as on form-7A & LOA i.e., (M/s Beijing Fert Technology Co., Ltd, Room 4196, Building 1, Shixingdong Jie, Badachu High Scientific and Technologic Garden,, Shijingshan District, Beijing China). Clarification is required.
105.	M/s ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt ELI-00103 Dossier# 733-C Submission date: 16/12/2022 Differential fee of 25000/- PKR submitted vide deposit slip No.57577383607.	Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor TijuanaRosarito 2000, 24702- B Ejido Francisco VilaTijuana, B.C.,C.P. 22235 Mexico FSC:USA valid till: 18-02-2023	Surgical Specialties-TM Bone Wax (Bone Wax) Code & Sizes: As per FSC Class-D Shelf Life:05 years	Deferred with final opportunity for the provision of following:- • Provide valid & notarized Design Examination certificate of the applied product. • Provide valid FSC (USA).
106.	M/s ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt ELI-00103 Dossier#756-C Submission date:16/12/2022 Differential fee of 25000/- PKR submitted vide deposit slip No. 094086423476	Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor TijuanaRosarito 2000, 24702- B Ejido Francisco VilaTijuana, B.C.,C.P. 22235 Mexico FSC:USA valid till: 18-02-2023	LOOK-TM SharpointTM-Sharpoin-TM plus (Plain or chromic Gut suture) Code & Sizes: As per FSC Class-D Shelf Life:05 years	Deferred with final opportunity for the provision of following:- • Provide valid & notarized Design Examination certificate of the applied product. • Provide valid FSC (USA).
107.	M/s ASTO Life	Legal Manufacturer:	Sharpoin-TM nylon	Deferred with final opportunity for the

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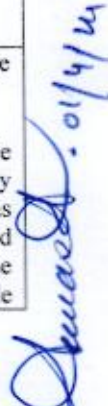
	<p>Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt ELI-00103 Dossier# 732-C Sub Submission date:16/12/2022</p> <p>Differential fee of 25000/-PKR submitted vide deposit slip No. 6900729595</p>	<p>Surgical Specialties Mexico S. DE R.L. DE CV Corredor TijuanaRosarito 2000, 24702- B Ejido Francisco VilaTijuana, B.C.,C.P. 22235 Mexico</p> <p>FSC:USA valid till: 18-02-2023</p>	<p>Sutures LOOK -TM nylon Sutures Sharpoint-TM Plus nylon Sutures ExactEtch-TM nylon Sutures (Non-absorbable nylon sutures) Code & Sizes: As per FSC Class-D Shelf Life:05 years</p>	<p>provision of following:-</p> <ul style="list-style-type: none"> • Provide valid & notarized Design Examination certificate of the applied product. • Provide valid FSC (USA).
108.	<p>M/s ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt ELI-00103 Dossier# 752-C Submission date:16/12/2022</p> <p>Differential fee of 25000/-PKR submitted vide deposit slip No.009026594</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor TijuanaRosarito 2000, 24702- B Ejido Francisco VilaTijuana, B.C.,C.P. 22235 Mexico</p> <p>FSC:USA valid till: 18-02-2023</p>	<p>Look-TM PTFE Sutures (Non-absorbable PTFE sutures) Code & Sizes: As per FSC Class-D Shelf Life:05 years</p>	<p>Deferred with final opportunity for the provision of following:-</p> <ul style="list-style-type: none"> • Provide valid & notarized Design Examination certificate of the applied product. • Provide valid FSC (USA).
109.	<p>M/s ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard I, Paragon City Barki Road, Lahore Cantt ELI-00103 Dossier# 731-C Submission date:16/12/2022</p> <p>Differential fee of 25000/-PKR submitted vide deposit slip No. 606413524</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor TijuanaRosarito 2000, 24702- B Ejido Francisco VilaTijuana, B.C.,C.P. 22235 Mexico</p> <p>FSC:USA valid till: 18-02-2023</p>	<p>Sharpoint-TM Silk Sutures Sharpoint-TM Plus Silk Sutures LOOK -TM Silk Sutures ExactEtch-TM Silk Sutures (Non-absorbable silk sutures) Code & Sizes: As per FSC Class-D Shelf Life:05 years</p>	<p>Deferred with final opportunity for the provision of following:-</p> <ul style="list-style-type: none"> • Provide valid & notarized Design Examination certificate of the applied product. • Provide valid FSC (USA).
110.	<p>M/s ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor</p>	<p>Quill-TM Polypropylene knotless tissue-closure device Stratafix -TM spiral</p>	<p>Deferred with final opportunity for the provision of following:-</p> <ul style="list-style-type: none"> • Provide valid & notarized Design

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	1, Paragon City Barki Road, Lahore Cantt ELI-00103 Dossier# 751- C Submission date:16/12/2022 Differential fee of 25000/- PKR submitted vide deposit slip No. 5586775206	TijuanaRosarito 2000, 24702- B Ejido Francisco VilaTijuana, B.C.,C.P. 22235 Mexico FSC:USA valid till: 18-02-2023	Polypropylene knotless tissue control device (Nonabsorbable polypropylene surgical sutures) Code & Sizes: As per FSC Class-D Shelf Life:05 years	Examination certificate of the applied product. • Provide valid FSC (USA).
111.	M/s Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3099-P 29-06-2022	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany FSC: Germany issuance: 06-06-2023	HLS Set Advanced 5.0/7.0 with Bioline coating (Heart Lung Support Set) Class-D Shelf life: 2 years Model: HLS Set Advanced 5.0/7.0 with Bioline coating	Deferred with final opportunity for following shortcoming:- • Provide Design examination certificate which is not provided
112.	M/s Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3108-P 29-06-2022	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany FSC: Germany issuance: 06-06-2023	Maquet HLS cannula (Heart Lung Support Set cannula, Arterial Cannulae) Class-D Shelf life: 3 years	Deferred for the provision of Design Examination certificate.
113.	M/s Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3081-P 29-06-2022	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany. FSC: Germany issuance: 06-06-2023	Maquet PSL Set (Extracorporeal Life Supports system) Class-D Shelf life: N/A Model/code: BE-PLS 2050	Deferred for the provision of Design Examination certificate.
114.	M/s Gulf Marketing International, Gulf House 10& 11-B/2,	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA	Diagnostar HBsAg Hepatitis B Surface Antigen Rapid Test (Serum/Plasma)	Deferred with final opportunity for the following: • Valid & embassy attested Free Sale Certificate of the reference country

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	Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04- 2021	Class: D Shelf-life: 24 months Size/Code: Fee: 50,000/- -dated 07- 04-2022.	wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin. • Valid Notarized Design Examination Certificate
115.	M/s Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04- 2021.	Diagnostar HCV Ab Rapid Test Cassette (Serum/Plasma) Class: D Shelf-life: 24 months Size/Code: Fee: 50,000/- -dated 07- 04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin. • Valid Notarized Design Examination Certificate
116.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04- 2021.	Diagnostar HIV (Human Immunodeficiency Virus) Rapid Test Cassette (Serum /Plasma) Class: D Shelf-life: 24 months Size/Code: Fee: 50,000/- -dated 07- 04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin. • Valid Notarized Design Examination Certificate
117.	M/s Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787,	Diagnostar Syphilis Ab Rapid Test (Cassette) (Serum /Plasma) Class: C Shelf-life: 24 months Size/Code:	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale



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	Tanki Said Pur Road, Rawalpindi ELI-00194	East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Fee: 50,000/- -dated 07-04-2022.	Certificate of the country of origin.
118.	M/s Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Toxoplasma gondii(Toxo)IgG/IgM Rapid Test (Cassette) (Serum/Plasma) Class: C Shelf-life: 24 months Size/Code: Fee: 50,000/- -dated 07-04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.
119.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Typhoid IgG/IgM Rapid Test Cassette (Serum/Plasma) Class: B Shelf-life: 24 months Size/Code: GCTYP-302a, GCTB-302a Fee: 25,000/- -dated 01-03-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.
120.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street	Diagnostar Urinalysis Strips Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/- -dated 07-04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.

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	ELI-00194	Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.		
121.	M/s Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar HCG One Test Pregnancy Test Strip (urine) Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/- -dated 07-04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.
122.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Dengue NS1 Antigen Rapid Test (Whole blood, serum, plasma) Malaria P.f./Pan Ag Rapid Test Cassette (Whole blood) Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/- -dated 07-04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.
123.	M/s Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized	Diagnostar H.pylori Ab Rapid Test Cassette (Whole blood, serum , plasma) Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/- -dated 07-04-2022.	Deferred with final opportunity for the following:- • Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.

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	ELI-00194	Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.		
124.	M/s Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Tuberculosis IgG/IgM Rapid Test Cassete Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/- -dated 07-04-2022.	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> Valid & embassy attested Free Sale Certificate of the reference country wherein the manufacturing site has been mentioned Or valid notarized FQA/CE Certificate along with the valid embassy attested Free Sale Certificate of the country of origin.
125.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (E2 Rapid Quantitative Test) Code: BT2212 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. Valid Legalized Free Sale Certificate. Valid notarized ISO13485. Valid Legalized FSC from reference country/CE Certificate & FQA.
126.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime	BIOTIME (AFP Rapid Quantitative Test) BT2402 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. Valid Legalized Free Sale Certificate. Valid notarized ISO13485. Valid Legalized FSC from reference country/CE Certificate & FQA.

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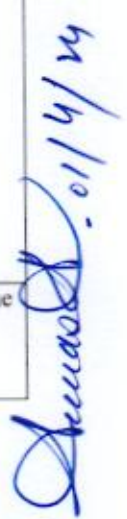
		Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .		
127.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7): Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BIOTIME (cTn/CK-MB/Myo Rapid Quantitative Test) BT2104 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11- 04-2022	Deferred with final opportunity for the following: <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
128.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7): Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BIOTIME (tPSA Rapid Quantitative Test) BT2404 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11- 04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
129.	Gulf Marketing International,	Legal manufacturer & manufacturer site	BIOTIME (PCT Rapid Quantitative	Deferred with final opportunity for the following:-

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	Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	(as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	Test) BT2301 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11-04-2022	<ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
130.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, PR. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BIOTIME (CRP Rapid Quantitative Test) BT2302 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
131.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd	BIOTIME (HbA1c Rapid Quantitative Test) BT2501 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.

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		<p>2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103</p> <p>Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.</p>		
132.	<p>M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194</p>	<p>Legal manufacturer & manufacturer site (as per FSC)</p> <p>Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China.</p> <p>Legal manufacturer (as per Form-7): Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103</p> <p>Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.</p>	<p>BIOTIME (25(OH)-D Rapid Quantitative Test)</p> <p>BT2801</p> <p>Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022</p> <p>Date of Application:11-04-2022</p>	<p>Deferred with final opportunity for the following:-</p> <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
133.	<p>M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194</p>	<p>Legal manufacturer & manufacturer site (as per FSC)</p> <p>Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China.</p> <p>Legal manufacturer (as per Form-7): Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103</p> <p>Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.</p>	<p>BIOTIME (Thyroid Profile : TSH/TT4/TT3Rapid Quantitative Test)</p> <p>BT2209, BT2210, BT2204</p> <p>Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022</p> <p>Date of Application:11-04-2022</p>	<p>Deferred with final opportunity for the following:-</p> <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
134.	<p>M/s Gulf Marketing International, Gulf House</p>	<p>Legal manufacturer & manufacturer site (as per FSC)</p>	<p>BIOTIME (Rapid Quantitative Tests for Renal Function Cys-C , NGAL , MAU)</p>	<p>Deferred with final opportunity for the following:-</p>



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	10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BT2601, BT2602, BT2603 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11- 04-2022	<ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
135.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BIOTIME (β-HCG PROG Rapid Quantitative Test) BT2202, BT2203 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11- 04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
136.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road,	BIOTIME (Total IgE Rapid Quantitative Test) BT2901 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11- 04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.

m/h. 10/04/24

(Handwritten signature)

		Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .		
137.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BIOTIME (FSH , LH , PRL .TESTOSTERONE Rapid Quantitative Test) BT2211, BT2205 , BT 2006 , BT 2007 , BT 2208 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11- 04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
138.	M/s Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022 .	BIOTIME (Ferritin Rapid Quantitative Test) BT 22701 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11- 04-2022	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the submitted Free Sale Certificate & Form 7-A. • Valid Legalized Free Sale Certificate. • Valid notarized ISO13485. • Valid Legalized FSC from reference country/CE Certificate & FQA.
139.	M/s Gulf Marketing International, Gulf House 10&11-B/2,	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime	BIOTIME (BIOT-YG-I FIA Analyzer) Class-B	Deferred with final opportunity for the following:- <ul style="list-style-type: none"> • Clarification regarding the difference of address in the

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	Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11- 04-2022	submitted Free Sale Certificate & Form 7-A. <ul style="list-style-type: none">Valid Legalized Free Sale Certificate.Valid notarized ISO13485.Valid Legalized FSC from reference country/CE Certificate & FQA.
140.	M/s Rech International, M-10, Block-6, PECHS, Near Hotel Faran, Off Shahrah-e- Faisal, Karachi (ELI-00257) [2741]	Legal Manufacturer: M/s SERF , 85 Avenue des Bruyeres 69150 Decines Charpieu, France FSC France Issuance Date (27-08-2018)	Reinforcement Cross KE Shelf life 5 years Class C	Deffered with final opportunity for the provision of following shortcomings:- <ul style="list-style-type: none">Valid and notarized CE/ Full quality assurance certificate, not providedStability studies not provided, only conclusion mentioned.
141.	M/s Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI- 00005)	Infomed Fluids S.r.l, Blvd Theodor Pallady, 50 032266 Sector 3-Bucharest Romania FSC: Romania (EU) Valid till: 26-05-2024	ACD-A Anticoagulant Solution 500ml Class : C, Shelf Life: 24 Months, Sizes and Model as per FSC, Date of submission :07- 04-2022	Deffered for submission of the valid and notarsied LOA
142.	M/s Maqsood Brothers, Office-503-B, 5 th Floor, Saima Trade Tower, LI Chundrigar Road Karachi ELI-00282 Date of submission 12-02-2021	Legal manufacturer Huaian Poly Medical Technology Corporation Address: No. 5 West Huaqing Road 223002 Huaian, PEOPLE'S REPUBLIC China Original Legalized Free Sale Certificate (FSC) dated, 29-07-21 SC Germany	LIFE CATH I.V Cannula Class- B Shelf Life: 5 Years	Deffered for clarification of type of cannula.
143.	M/s Kaf Surgical & Disposable Equipement,	Manufactured By: Plasti Lab S.A.R.L. Roumeih, El Metn Industrial area, Main Raod El Khoury	JRZ I.V Cannula with Wings with injection port Intravenous Cannula all Sizes	Deffered with final opportunity for clarification/ provision of below mentioned documents:- <ul style="list-style-type: none">Free Sale certificate statement from

M/s Kaf Surgical & Disposable Equipement

	HM Disposable Office No. 24-25, Mezzanine Floor, Medicine Corner, KachiGali No.2, Marriot Road, Karachi.	Building, P.O. Box 70407, Lebnon. (FSC not provided only statement provided issued by third party.	Class B Shelf Life Not provided Sizes: G-14, G-16, G-18, G-20, G-22, G-24, G-26	Lebanon is not from the health regulatory body of Lebanon. Provide Free Sale Certificate from the relevant regulatory body attested by Embassy of Pakistan in Lebanon <ul style="list-style-type: none"> The reference country Free Sale Certificate from Netherland is issued for Egypt. Submit original valid Embassy attested Free Sale Certificate for the applied product issued for Pakistan. Fee deposit slips mentioned on cover letter are not present in the submitted dossier. Submit original fee deposit slips Provide Essential Principles of Safety and Performance for the applied product Provide label for all sizes applied Clearly state the shelf life required
144.	M/s Endovision Enterprises, A-173, Block - 3, Gulistan-e-Jauhar, Karachi Establishment License No: ELI 00730	M/s CHANGZHOU NEW DISTRICT GARSON MEDICAL STENT APPARATUS Co., Ltd Address: No. 06, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu, China Embassy attested FSC: China, Valid until: 15-05-2025	Garson Flexent Esophageal Stent System Coverd Sizes and Codes: As per FSC Class C Shelf life: 1 years Application submission date: 03-11-2021 Fee submitted: Rs 50,000/-	Deferred with final opportunity for submission of the following:- <ul style="list-style-type: none"> The product is from non reference country the valid and notarized CE certificate. Clarify the name of the product. Revise Form 7A as per FSC. Provide brochure of the device.
145.	M/s Endovision Enterprises, A-173, Block - 3, Gulistan-e-Jauhar, Karachi Establishment License No: ELI 00730 Application submission date: 03-11-2021	M/s CHANGZHOU NEW DISTRICT GARSON MEDICAL STENT APPARATUS Co., Ltd Address: No. 06, Huanbao 8th Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu, China Embassy attested FSC: China, Valid until: 15-05-2025	Garson Flexent Esophageal Stent System Partially Coverd Sizes and Codes: As per FSC Class C Shelf life: 1 years Fee submitted: Rs 50,000/-	Deferred with final opportunity for submission of the following:- <ul style="list-style-type: none"> The product is from non reference country the valid and notarized CE certificate. Clarify the name of the product. Revise Form 7A as per FSC. Provide brochure of the device

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2. In the light of decision of MDB in its 37th meeting wherein Board decided that once the firm has submitted original, valid and notarized/Embassy attested documents at the time of submission of application for registration/enlistment and the same are expired during the processing of application, the firm shall only submit valid and original (where applicable) documents without notarization/Embassy attestation.

3. It is requested to furnish the requisite information/documents mentioned in last column against each within 30 days after uploading of this letter on official website of DRAP.


(AYYAZ AHMAD)
Additional Director (MDMC)
Secretary MDB



No.F.4-1/2024-MD (M-65)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 1st April, 2024

Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE - SUBMISSION OF DEFICIENT INFORMATION/ DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 65th meeting held on 25th and 26th January, 2024 and Board deferred these applications being deficient of the information/documents as specified in last column (IV) of the Table below: -

Sr. No.	Name & Address of Establishment	Name of Medical Devices with Size	Decision
1.	Ophth Pharma (Pvt.) Ltd Plot No. 241, Sector 24, Korangi Industrial Area, Karachi Pakistan License No. ELM-0055	BT PGLA Sutures Poly (glycolide/l-lactide) Class: B Shelf-life: 5 years Sizes: 0 x 12 sachet, 1 x 12 sachet 2 x 12 sachet, 2/0 x 12 sachet 3/0 x 12 sachet, 4/0 x 12 sachet 5/0 x 12 sachet, 6/0 x 12 sachet 7/0 x 12 sachet, 8/0 x 12 sachet	Deferred for confirmation of class of the product & manufacturing facility/section.
2.	Ophth Pharma (Pvt.) Ltd Plot No. 241, Sector 24, Korangi Industrial Area, Karachi Pakistan License No. ELM-0055	Surgimesh Polypropylene Monofilament Knitted non-absorbable mesh undyed Class: D Shelf-life: 5 years Sizes: 6 x 11 cm (1 x 3) 15 x 15 cm (1 x 3) 30 x 30 cm (1 x 3)	Deferred for confirmation of manufacturing facility/section.
3.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [209-6L] 1. Absorbent Cotton Wool Section (Non- Sterile) 2. Crepe Bandage Section (Non-Sterile) 3. Cotton bandage section 4. Gauze Section (Non- Sterile) 5. Plaster of Paris (POP) section 6. Tulle Section	SURGI GRIP Surgical Adhesive Paper Tape Bandage Surgical Adhesive Paper Tape Bandage Class: A Shelf-life: 5 Years Sizes: Fee: 5,000	Deferred for clarification / verification of the facility for the manufacturing of the said product.

4.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [210-6L] 1. Absorbent Cotton Wool Section (Non- Sterile) 2. Crepe Bandage Section (Non-Sterile) 3. Cotton bandage section 4. Gauze Section (Non- Sterile) 5. Plaster of Paris (POP) section 6. Tulle Section	ALCO SWAB Alcohol Swab Class: A Shelf-life: 5 Years Sizes: Fee: 5,000	Deferred for clarification / verification of the facility for the manufacturing of the said product
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2. It is requested to furnish the requisite information/documents within 30 days after uploading of this letter on official website of DRAP.


 (AYYAZ AHMAD)
 Additional Director (MDMC)/
 Secretary MDB

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