



No.F.4-9/2023-MD (M-60)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad the 5<sup>th</sup> September, 2023

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 60<sup>th</sup> meeting held on 10<sup>th</sup> August, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Decision
(I)	(II)	(III)	(IV)	(V)
1.	M/s Verizon. 60-D F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) 3033-P 07-06-2022	<b><u>Legal Manufacturer:</u></b> Cook Inc. 750 Daniels Way, Bloomington In USA, 47404  FSC: U.S.A Valid till: 12/07/2022	Cook Medical Multipurpose drainage catheter ultrathane (Percutaneous Biliary drainage catheter and sets)  Class-C Shelf life: 3 years Codes & Sizes: As per FSC	<b>Deferred</b> for the provision of following documents: Original and valid FSC, ISO 13485 and FQA certificates.  Also original documents reference that in which application original documents are attached.
2.	M/s Muslim Scientific Corporation, 3 Syed Moj Darya Road 3 <sup>rd</sup> Floor of Building  <b><u>Warehouse</u></b> <b><u>Address:</u></b> House # 57 PAF Colony Zarar Shaheed Road, Lahore  ELI: 00431 3036-P 13-06-2022	<b><u>Legal Manufacturer:</u></b> Taidoc Technology Corporation 127, Wugong 2nd Road, Wugu District, New Taipei City, Taiwan 248	CC TD-4116 (CC Advance Glucometer+ strips)  Class-C  Shelf life: AS per stability study	<b>Deferred</b> for the provision of following documents: All the relevant documents as per Form-7A.  Documents submitted are Form-7A, fee and Technical data of the device applied only.
3.	M/s Sanwa Trading Corporation, Office No. G-88, Pindi Cricket Stadium Double Road, Rawalpindi  ELI: 3754-P 09-01-2023	<b><u>Legal Manufacturer:</u></b> M/s Cooper Surgical Inc. 95 Corporate Drive Trumbull, Connecticut 06611, USA  FSC: Not found	Sure-Pro Ultra Embryo Replacement catheter with Obturator (Embryo replacement Catheter)  Class-C Shelf Life: 3 years Codes & Sizes: As per FSC	<b>Deferred</b> for the provision of following documents: all the relevant documents as per form-7A. also the device applied falls in Class-C whereas the fee submitted is only 5000/-, submit differential fee of 45000/- Rs.

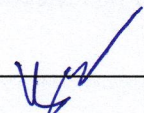


4.	M/s Tech Zone, 764 Askari 9 Zarar Shaheed Road Cantt Lahore, WH: Ground Floor, Weal House 8 Faiz road, Lahore  ELI: 00040 736-P 05-11-2021	<b>Legal Manufacturer:</b> Pikdare S.P.A, Via Saldarini Catelli 10, 22070 Casnate con Bernate COMO Italy  FSC: Italy Date of Issue: 14/05/2019	PIC Solution Soffix Transparent (PE Adhesive Tape Role)  Class-A  Shelf Life: 5 years  Codes & Sizes: As per FSC	<b>Deferred</b> for the provision of following documents: Original, valid and notarized LOA. Valid FSC  Essential Principle checklist.
5.	M/s Tech Zone, 764 Askari 9 Zarar Shaheed Road Cantt Lahore, WH: Ground Floor, Weal House 8 Faiz road, Lahore  ELI: 00040 734-P 05-11-2021	<b>Legal Manufacturer:</b> Pikdare S.P.A, Via Saldarini Catelli 10, 22070 Casnate con Bernate COMO Italy  FSC: Italy Date of Issue: 14/05/2019	Pic Solution Soffix PORE (Surgical Paper Tape)  Class-A  Shelf Life: 5 years  Codes & Sizes: As per FSC	<b>Deferred</b> for the provision of following documents: Original, valid and notarized LOA. Valid FSC  Essential Principle checklist.
6.	M/s Moody Global Services, Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926 Dossier# 573-C Submission date: 11/11/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b> M/S Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China <b>FSC: Germany issued on 22-06-2021</b>	Lifotronic Neuronen -Spezifische Enolase (e CLIA)  Code & Sizes: As per FSC Class-C Shelf Life: 18 months Temperature: 2-8 °c	<b>Deffered</b> for the provision of following:  FSC of Reference country & FSC of country of origin are not provided
7.	M/s Moody Global Services, Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926 Dossier# 1002-C Submission date: 26/12/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b> M/S Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China <b>FSC: Germany issued on 22-06-2021</b>	Lifotronic Total Prostate specific Antigen(e CLIA) Code & Sizes: As per FSC Class-C Shelf Life: 18 months Temperature: 2-8 °c	<b>Deffered</b> for the provision of following:  FSC of Reference country & FSC of country of origin are not provided
8.	M/s A&E Medical, 323-ATA Turk Block new Garden Town, Lahore ELI: 00023 Dossier# 4017-P Submission date: 13/07/2023	<b>Legal Manufacturer:</b> Sino Medical Sciences Technology Inc. 2nd Floor, TEDA Biopharm Res, Building, B#5, 4th St. TEDA, Tianjin China 300457	SC HONKYTONK PTCA BALLOON DILATATION CATHETER (PTCA BALLOON CATHETER) Codes& Sizes: As per FSC Class-B	<b>Deffered</b> for the provision of following:  Establishment license is expired  Product is from a non-reference country and the applicant has not provided FSC of any reference country/ CE mark



	<b>Evaluator:</b> DD-III	Original FSC: China Valid till: 29/08/2023	Shelf Life: 36 months Temperature: 0 to +50 °c	certificate or WHO prequalification for this applied product.
9.	M/s A&E Medical, 323-ATA Turk Block new Garden Town, Lahore ELI: 00023 Dossier# 4016-P Submission date: 13/07/2023 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b> Sino Medical Sciences Technology Inc. 2nd Floor, TEDA Biopharm Res, Building, B#5, 4th St. TEDA, Tianjin China 300457 Original FSC: China Valid till: 29/08/2023	NC ROCKSTAR PTCA BALLOON DILATION CATHETER (PTCA BALLOON CATHETER) Codes& Sizes: As per FSC Class-B Shelf Life: 36 months Temperature: 0 to +50 °c	<b>Deferred</b> for the provision of following:  Establishment license is expired  Product is from a non-reference country and the applicant has not provided FSC of any reference country/ CE mark certificate or WHO prequalification for this applied product.
10.	M/s Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061)  2987  <b>Date (R&amp;I)</b> 31-8-2020	<b>Legal Manufacturer:</b> Radiometer Medical ApS Akandevej 21 2700 Bronshoj- Denmark  <b>Manufacturing site:</b> SenDx Medical Inc. 1945 Palomar Oaks Way Carlsbad, CA92011 USA  FSC Denmark Valid till 3-1-2021	ABL9 Blood gas electrolyte and metabolite analyzer  Class C  Code 393-899  Shelf Life: N/A  Fee: 50,000/-	<b>Defer</b> for the provision of the followings:-  Original, valid & notarized LoA.  Valid ISO 13485 and FQAS certificates.  Original & valid FSC of Denmark.
11.	M/s UDL Distribution Pvt Ltd, I-D-13, Sector 30, Korangi Industrial Area Karachi (ELI-00073)  3044  <b>Date (R&amp;I)</b> 6-8-2020	<b>Legal Manufacturer:</b> Arrow International, Inc (Subsidiary of Teleflex Inc.) 2400 Bernville Road Reading, PAUSA 19605  <b>Manufacturing site:</b> Arrow International, Inc.16 Elizabeth Dr Chemsford, MA USA 01824  FSC US FDA Valid till: 15-4-2020	AC3 Optimus Intra-Aortic Balloon Pump  Class C  Code IAP-0700 IAP-0701  Service Life: 15 years  Fee: 50,000/-	<b>Defer</b> for the provision of the followings:  Submission of the latest status of the device whether it is available or discontinued in the country of origin i.e. USA as the same product was recalled by US FDA back in 2020.  Original, valid & notarized LoA.  Valid ISO 13485 and FQAS certificates.  Original, valid & Embassy attested FSC of US FDA.  Notarizes credentials of the manufacturer.  EPSP DoC
12.	M/s Ghazali Brothers, 1st Floor Azzainab court Campbell Street, Karachi, PAKISTAN ELI-00240	M/s Huaiyin Medical Instruments Co., Ltd No.8 West Ming Yuan Road, Huaian City, Jiangsu Province, China  1. Original Exporter & Manufacturer	CARE CATGUT SUTURES  CLASS -B  SHELF LIFE 5 YEARS	<b>Deferred</b> for submission of the following documents:  Apply on Form 7A as per MDR as new Medical Device.  The product falls in class D therefore submit differential fee of RS 25000/-



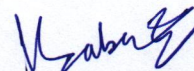
		<p>relationship explanation letter</p> <p>2. Original Agency agreement notarized</p> <p>3. Original Credentials of Manufacturer Abroad notarized</p> <p>4. Embassy attested Original Free Sale Certificate china</p> <p>5. Original Full Quality assurance notarized</p> <p>6. Original Declaration of conformity (DoC) notarized</p>		<p>Submit notarized and valid Design Examination certificate</p> <p>Submit valid FSC in the country of origin and CE marking certificates or valid and embassy attested FSC of RRA.</p> <p>Clarify the brand name since it is not aligned with the FSC.</p>
13.	<p>M/s Ghazali Brothers, 1st Floor Azzainab court Campbell Street, Karachi, PAKISTAN</p> <p><b>ELI-00240</b></p>	<p>M/s Huaiyin Medical Instruments Co., Ltd No.8 West Ming Yuan Road, Huaian City, Jiangsu Province, China</p> <p>All original documents below</p> <p>1. Original Full Quality assurance notarized</p> <p>2. Original Production Quality Management System notarized</p> <p>3. Original Declaration of conformity (DoC)</p> <p>4. Below Originals In Care Catgut Renewal File</p> <p>5. Original Exporter &amp; Manufacturer relationship explanation letter</p> <p>6. Original Agency agreement notarized</p>	<p>CARE SILK BRAIDED SUTURES; CLASS -B, SHELF LIFE 5 YEARS (PACKING) AS PER SIGNED ANNEXURE-A</p>	<p><b>Deferred</b> for submission of the following documents:</p> <p>Apply on Form7A as per MDR as new Medical Device.</p> <p>The product falls in class C therefore submit differential fee of RS 25000/-</p> <p>Submit valid FSC in the country of origin and CE marking certificates or valid and embassy attested FSC of RRA.</p> <p>Clarify the brand name since it is not aligned with the FSC</p> 



		7. Original Credentials of the manufacturer abroad notarized		
		8. Embassy attested Free Sale Certificate china.		

2. In the light of decision of MDB in its 37<sup>th</sup> meeting wherein Board in order to make quick disposal of cases decided for the firms who have submitted original, valid and Notarized/Embassy attested documents at the time of submission of application for registration/enlistment and is expired during the processing of applications, such firms shall only submit valid and original (where applicable) documents.

3. It is requested to furnish the requisite information/documents mentioned in last column against each within 20 days after uploading of this letter on official website of DRAP.



**(BABAR KHAN)**  
Additional Director (MDMC)/  
Secretary MDB





No.F.4-9/2023-MD (M-60)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad the 5<sup>th</sup> September, 2023

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 60<sup>th</sup> meeting held on 10<sup>th</sup> August, 2023 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 sizes	Decision
(I)	(II)	(III)	(IV)
1.	M/s Paktex Industries, 2.5th KM Tatlay Road Saroya Abad, Kamoke. [ELM No.0025]  <b>Approved Sections:</b> a. Cotton Bandage b. Surgical Gauze (Sterile/Non-Sterile) c. Crepe Bandage d. Alcohol Gauze e. Adhesive Section f. Medicated Tulle Gauze/Paraffin Gauze Section	<b>NEOCARE CORD CLAMP</b> Umbilical cord clamp_sterile Class-A Shelf Life: 5 Years Sizes & Codes  <b>Standard Size in different colors</b> i)-Pink ii)-White- iii)-Blue iv)-Green v)-Red vi)-Black  Fee : 5000/- with slip No. 4370381754 dated 5-10-2021	<b>Deferred</b> for the approval of the required section & undertaking that the fee slip will not be used for any other product/process of DRAP.
2.	M/s Paktex Industries, 2.5th KM Tatlay Road Saroya Abad, Kamoke. [ELM No.0025]  <b>Approved Sections:</b> a. Cotton Bandage b. Surgical Gauze (Sterile/Non-Sterile) c. Crepe Bandage d. Alcohol Gauze e. Adhesive Section f. Medicated Tulle Gauze/Paraffin Gauze Section	<b>Shoe guard</b> Disposable shoe cover Class-A Shelf Life: 5 Years Sizes & Codes  <b>Standard Size in different colors</b> i)-Pink ii)-White- iii)-Blue iv)-Green v)-Red vi)-Black  Fee : 5000/- with slip No. 04324665659 dated 5-10-2021	<b>Deferred</b> for the approval of the required section & undertaking that the fee slip will not be used for any other product/process of DRAP.

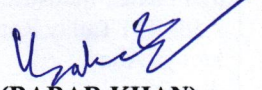
Deferred Letters of 60<sup>th</sup> Meeting of MDB (10-08-2023)

Page 1 of 2



3.	<p>M/s Paktex Industries, 2.5th KM Tatlay Road Saroya Abad, Kamoke. [ELM No.0025]</p> <p><b>Approved Sections:</b></p> <p>a. Cotton Bandage b. Surgical Gauze (Sterile/Non-Sterile) c. Crepe Bandage d. Alcohol Gauze e. Adhesive Section f. Medicated Tulle Gauze/Paraffin Gauze Section</p>	<p><b>Pakband Disposable Surgeon/Operation Theatre Cap</b> Class-A Shelf Life: 5 Years Sizes &amp; Codes</p> <p><b>Standard Size in different colors</b> i)-Pink ii)-White- iii)-Blue iv)-Green v)-Red vi)-Black</p> <p>Fee : 5000/- with slip No. 609659184849 dated 5-10-2021</p>	<p><b>Deferred</b> for the approval of the required section &amp; undertaking that the fee slip will not be used for any other product/process of DRAP.</p>
4.	<p>M/s Whitesun Pharma, Marri road, Kamoke, Gujranwala ELM-0016 Dated: 09/03/2020</p> <p><b>Approved section:</b></p> <p>Cotton Bandage Cotton Crepe Bandage Non-Sterile Surgical Gauze</p>	<p><b>Nexcare Absorbent Cotton Wool</b> Absorbent Cotton</p> <p><b>Class:</b> Class: A <b>Shelf-life:</b> Years 3-years <b>Sizes:</b> 50 GRAMS 100 GRAMS 200 GRAMS 300 GRAMS 400 GRAMS 500 GRAMS <b>Fee Challan No.</b> Rs. 5000/- (730160291 dated:31/10/22)</p>	<p><b>Deferred</b> for the approval of the required section.</p>

2. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.

  
**(BABAR KHAN)**  
 Additional Director (MDMC)/  
 Secretary MDB