

DECISIONS OF THE 30TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 23-02-2021

1. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.

| S.No | Name of Establishment | Director/Proprietor/partners | Cold Chain (Yes/No) | Decision |
|------|--|--|---------------------|--|
| 1. | M/s WIS international, Office No. 910, 9 th Floor, Business Avenue Building, Plot No. 26-A, Block-6, P.E.C.H.S. Karachi. | Mr. Zhan Xiang (CEO) Mr. Goa Hua | No | Approved for storage of non-cold chain medical devices. |
| 2. | M/s Spectra Baby Pakistan, Ideal Centre, A-18/19, Block 7 & 8, KCHSU Ltd, Karachi. | Mr. Fawad Ijaz Khan Sehrish Fawad Khan | No | Approved for storage of non-cold chain medical devices. |
| 3. | M/s Al Madina International Co, Office No. 306/11, Trade Tower, Altaf Hussain Road, New Challi, Karachi. Godown: 5&6, Bagasra Square, G, Alana road, Khaddar, Karachi. | Muhammad Qazzafi | -do- | Approved for storage of non-cold chain medical devices. |
| 4. | M/s Spine Marketing Services, Office No. 2, Mezzanine Floor, Building 6C, Jami Commercial Street No. 12, Lane 26, D.H.A. Phase-7, Karachi. | Mr. Zafar Abbas | No | Approved for storage of non-cold chain medical devices. |
| 5. | M/s Tycoon Technology, Flat No. 3, Aamir Plaza Khyber Super Market, Saddar Cantt, Peshawar. | Mr. Muhammad Adnan Mr. Arsalan Rafiq Mr. Tahir Ameen | No | Approved for storage of non-cold chain medical devices. |
| 6. | M/s Mod Scientific Traders, 3 Mouj | Mr. Mubashar Ahmad | No | Approved for storage of non-cold |

| | | | | |
|----|---|------------------|----|--|
| | Darya Road, Lahore. Godown: Same as above. | | | chain medical devices. |
| 7. | M/s Class 1 Technology, Murree Heights, Plot No. SB 31, Block-13/C, Shop No. 3, 4 University Road, Gulshan-e-Iqbal, Karachi. Godown: Same as above. | Syed MugheezAlam | No | Approved for storage of room temperature medical devices. |

2. APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.

| S.No | Name of Establishment | Address | Name of Qualified Person | Name of QC Incharge |
|------|-----------------------|---|--|--|
| 1. | M/s General Pharma | Nazir Farm Road, 3-KM, G.T. Road (KotliWagha), Kamoke, District Gujranwala. | Mr. Muhammad Ali Afaq (Production Incharger) (M.Sc. Chemistry) | Mr. Muhammad Saeed QC Incharge (Pharm-B, M.Phil) |

Decision: The Board discussed and approved the renewal of DML (Establishment License) of M/s General Pharma, Nazir Farm Road, 3-KM, G.T. Road (KotliWagha), Kamoke, District Gujranwala.

3. POST LICENSE VARIATIONS.

3.1.

M/s FDS (Pvt) Ltd., Flat No.8, 1st Floor, Ganga Ram Mansion, Shahrah-e-Quaid-e-Azam, Lahore has requested for approval of change of qualified/technical person in their ELI-00475 issued on 24-01-2020 as per detail given below:-

| |
|----------------------------------|
| Existing Technical Person |
|----------------------------------|

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|----------------------------------|
| Proposed Technical Person |
|----------------------------------|

| | |
|---|--|
| Mr. Inam Ul Haq Chaudry, House No.489, Street No.13, Gulistan Colony, DharamPura, Lahore. CNIC # 35201-2991193-5 | Mr. Umair Waqas, House NO.75, Street No.3, Block-D, Mohalah Punjab Cooperative Housing Society, Lahore Cantt, Lahore. CNIC # 38403-5155654-3 (Pharm-D |
|---|--|

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person as mentioned below :-

| Previous Technical Person | New Approved Technical Person |
|---|--|
| Mr. Inam Ul Haq Chaudry, House No.489, Street No.13, Gulistan Colony, DharamPura, Lahore. CNIC # 35201-2991193-5 | Mr. Umair Waqas, House NO.75, Street No.3, Block-D, Mohalah Punjab Cooperative Housing Society, Lahore Cantt, Lahore. CNIC # 38403-5155654-3 (Pharm-D |

3.2.

Case of M/s M.M Brothers, Karachi for grant of establishment license to import medical devices under Medical Devices Rules, 2017 was placed before the MDB in its 26th meeting held on 06-01-2021 and decided as per detail given below:-

| | | | | | |
|----|---|------------------|------|----|--|
| 1. | M/s M.M. Brothers, Shop # 36, Madina Centre, Kutchi Gali No.1, Denso Hall, Karachi. | Mr. Mujeeb Ahmed | -do- | No | Approved for storage of room temperature medical devices. |
|----|---|------------------|------|----|--|

Decision: The MDB approved the insertion of godown address " House No. 12 KMCHS, BLK 7/8, Near Hill Park, Karachi" in already approved Establishment License to import medical devices.

3.3.

Case of M/s Silpha Labs (Pvt) Ltd, Karachi for grant of establishment license to import medical devices under Medical Devices Rules, 2017 was placed before the MDB in its 26th meeting held on 06-01-2021 and decided as per detail given below:-

| Name of Establishment | Director/Proprietor/ r/ partners | Name of panel Inspector (s) | Cold Chain (Yes/No) | Decision |
|---|--|--|---------------------|--|
| M/s Silpha Labs (Pvt) Ltd, 99/6, Gulshan-e-MehrunNisa, Ibrahim Hyderi, Korangi Creek, Karachi | Mr. Taimur Usman Mr. Faizan Usman | Dr. RafiqAlam Khan, Meritorius Professor, Ziauddin University, Karachi. Mrs. Hira Bhutto, AD, CDL, Karachi. | No. | Approved for storage of room temperature medical devices. |

Decision: The MDB approved the correction of name of one of the partner of M/s Silpha Labs (Pvt) Ltd, Karachi from Mr. Faizan Usman to Mr. Faiz Fasih Zafar Usman.

4. POST REGISTRATION VARIATIONS.

4.1.

M/s Al-Hamd Enterprises, FL-11/1/1 , Block - 6, Gulshan-e-Iqbal , Karachi has applied for change of manufacturer name and address from M/s Suzhou Colour-way Enterprise Development Co Ltd Dongqiao Industrial Area, Xiangcheng District, Suzhou, China to M/s Suzhou Colour-Way New Material Co. Ltd., No.20, Anmin Road, Huangdai Town, Xiangcheng District, 215152 Suzhou City, Jiangsu Province china for their following registered medical devices for import as per detail given below:-

| S.No. | Regn No. | Name of Medical Device | Existing Name and address of Manufacturer | Proposed Name of and Address of Manufacturer |
|--------------|-----------------|---|---|---|
| 1 | MDIR-0001236 | Surgitex Latex Surgical Gloves (Powdered) [6, 6.5, 7, 7.5, 8, 8.5] | M/s Suzhou Colour-way Enterprise Development Co Ltd Dongqiao Industrial Area, Xiangcheng District, Suzhou, China. | M/s Suzhou Colour-Way New Material Co. Ltd., No.20, Anmin Road, Huangdai Town, Xiangcheng District, 215152 Suzhou City, Jiangsu Province china. |
| 2 | MDIR-0001593 | Surgitex Latex Surgical Gloves (Powder-free) [Sizes: 6, 6.5, 7, 7.5, 8, 8.5] | -do- | -do- |

Decision: The MDB discussed the case and decided to approve the change of manufacturer name and address of below mentioned medical devices:-

| S.No. | Regn No. | Name of Medical Device | Previous Name and address of Manufacturer | New Approved Name of and Address of Manufacturer |
|--------------|-----------------|---|---|---|
| 1 | MDIR-0001236 | Surgitex Latex Surgical Gloves (Powdered) [6, 6.5, 7, 7.5, 8, 8.5] | M/s Suzhou Colour-way Enterprise Development Co Ltd Dongqiao Industrial Area, Xiangcheng District, Suzhou, China. | M/s Suzhou Colour-Way New Material Co. Ltd., No.20, Anmin Road, Huangdai Town, Xiangcheng District, 215152 Suzhou City, |

| | | | | |
|---|--------------|--|------|----------------------------|
| | | | | Jiangsu Province china. |
| 2 | MDIR-0001593 | Surgitex Latex Surgical Gloves (Powder-free) [Sizes: 6, 6.5, 7, 7.5, 8, 8.5] | -do- | -do- |

4.2.

M/s AGP Limited, B-23-C, SITE, Karachi has requested for correction in address of manufacturer of their following registered medical devices for import (typographical mistake) as per detail given below:-

| S.No. | Red No. | Name of Medical Device | Address of manufacturer mentioned on registration letter | Correction required in manufacturer address |
|-------|--------------|---------------------------------------|--|--|
| 1. | MDIR-0002117 | oneject Auto Disable Syringe (0.05ml) | M/s PT Onject Indonesia, Olympic Raya Kav, B9 KawasanIndustriSentul Bogor 16810-Indonesia. | M/s PT Onject Indonesia, JI Olympic Raya Kav, B9 KawasanIndustriSentul Bogor 16810-Indonesia. |

Decision: The MDB approved the correction of manufacturer address in already registered medical device as mentioned below:-

| S.No. | Red No. | Name of Medical Device | Previous address of manufacturer mentioned on registration letter | Correct address of manufacturer |
|-------|--------------|---------------------------------------|--|--|
| 1. | MDIR-0002117 | oneject Auto Disable Syringe (0.05ml) | M/s PT Onject Indonesia, Olympic Raya Kav, B9 KawasanIndustriSentul Bogor 16810-Indonesia. | M/s PT Onject Indonesia, JI Olympic Raya Kav, B9 KawasanIndustriSentul Bogor 16810-Indonesia. |

4.3.

M/s Premier Sales (Private) Limited, Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi has informed that their product **BD Ultra Fine™ II Insuline Syringes (1ml)** Manufactured by M/s Becton Dickinson and Company, 1 Becton Drive Franklin Lakes, New Gersey 07417, USA, has been granted registration vide No. MDIR-0000001 dated 26-10-2018 and currently being marketed in a pouch pack of 100s. They have requested to allow them for blister packing.

Decision: The MDB discussed and acceded to the request of the firm and allowed blister packing of BD Ultra Fine™ II Insuline Syringes (1ml).

4.4.

M/s Digital Imaging Systems, 121-Habitat Apartments, Shadman-II, Ghaus-ul-Azam Road, Lahore has requested for addition of new manufacturing site of their already registered medical device namely AMPLATZER Guidewire (Catheter Guidewire) (Regn. No. MDIR-0000446) as per detail mentioned below: -

| Regn. No. | Name of Medical Devices. | Existing Manufacturing Site | Proposed Additional Manufacturing Site. |
|--------------|--|--|---|
| MDIR-0000446 | AMPLATZER Guidewire (Catheter Guidewire) | M/s Abbott Medical 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442. | M/s Lake Region Medical Limited, Butlers Land, New Ross, Wexford Ireland. |

Decision: The Board approved the additional manufacturing site for below mentioned medical advice of M/s Digital Imaging System, Lahore as mentioned below:-

| Regn. No. | Name of Medical Devices | Existing Manufacturing Site | Proposed Additional Manufacturing Site. |
|--------------|--|--|---|
| MDIR-0000446 | AMPLATZER Guidewire (Catheter Guidewire) | M/s Abbott Medical 5050 NATHAN LANE NORTH Plymouth, Minnesota USA 55442. | M/s Lake Region Medical Limited, Butlers Land, New Ross, Wexford Ireland. |

4.5.

The case of M/s Sy'ah Impex, Karachi for grant of renewal of registration of below mentioned medical device for import was placed before the MDB in its 27th meeting held on 21-01-2021 and approved:-

| | | | | | |
|-----------|---|---|--|----------------------------------|-----------------|
| 1. | M/s SY'AH IMPEX, 1-6/15 Sector No. 5, Korangi Industrial Area Karachi Pakistan ELI: 00440 (Renewal) Evaluator: AD-III | Legal Manufacturer: M/s Changzhou Tongda Medical Appliance Co., Ltd. Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. FSC MHRA issuance 06-12-2016, FSC China Valid till: 2020.09.13 | ShifaAotu- destructive Syringe Class-B Shelf Life: 3 years Sizes: 0.5cc, 1cc, 2cc, 3cc & 5cc | Auto- destructive syringes | Approved |
|-----------|---|---|--|----------------------------------|-----------------|

Decision: The MDB approved the correction of shelf life i.e. from 3 years to 5 years for above mentioned medical devices.

4.6.

The case of M/s Global Marketing Services, Rawalpindi for grant of registration of below mentioned medical device for import was placed before the MDB in its 27th meeting held on 21-01-2021 and approved:-

| | | | | | | |
|-----------|---|--|--|--|---|------------------|
| 1. | M/s Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi | Legal Manufacturer: M/s BioMerieux SA 376 Chemin De l'Orme 69280 Marcy l'Etoile, France Manufacturing Site: M/s BioMerieux SA 3 Route de Port Michand 38390 La Balme Les Grottes, France (FSC France Issuance Date: 05-07-2019) | E-Test Class B Shelf Life: 24 Months Codes & Sizes as per FSC | Etest is quantitative technique for determining the antimicrobial susceptibility of Gram-negative and Gram-positive aerobic bacteria such as enterobacteria cea. | Deferred for 19th meeting provision of valid and original agency agreement from the country of origin duly notarized. Now, the firm has submitted the shortcomings | Approved. |
|-----------|---|--|--|--|---|------------------|

2. It is submitted that the shelf life of the above mentioned medical device was mentioned as 24 Months while the correct shelf life is mentioned below: -

| Reference | Num | Shelf life (Months) |
|-----------------------------------|--------|---------------------|
| AMPHOTERICIN-B AP 32 WW B100 | 526308 | 60 |
| ITRACONAZOLE IT 32 WW S30 | 412380 | 24 |
| POSACONAZOLE POS 32 WW S30 | 532100 | 60 |
| Ceftaroline CPT 32 WW B30 | 537500 | 24 |
| AMIKACIN AK 256 WW S30 | 412219 | 24 |
| Amoxi/clav 2/1XL 256 WW S30 | 412241 | 24 |
| AMPICILLIN AM 256 WW S30 | 412253 | 24 |
| Azithromycin Z 256 WW S30 Pack/30 | 412257 | 24 |
| Aztreonam AT 256 WW S30 | 412259 | 24 |
| Benzylpenicil PG 256 WW S30 | 412263 | 24 |
| Ceftazidime TZ 256 WW S30 | 412293 | 24 |
| Ceftriaxone TX 256 WW S30 | 412301 | 24 |
| CEFUROXIME XM 256 WW S30 | 412305 | 14 |
| CHLORAMPHENICOL CL 256 WW S30 | 412309 | 24 |
| Ciprofloxacin CI 32 WW S30 | 412311 | 24 |
| Clindamycin CM 256 WW S30 | 412315 | 24 |
| Erythromycin EM 256 WW S30 | 412334 | 24 |
| FLUCONAZOLE FL 256 WW S30 | 412350 | 24 |
| GENTAMICIN GM 256 WW S30 | 412368 | 24 |
| Imipenem IP 32 WW S30 | 412374 | 24 |
| Kanamycin KM 256 WW S30 | 412382 | 60 |

| | | |
|--|--------|----|
| METRONIDAZOLE MZ 256 WW S30 | 412404 | 24 |
| Tetracycline TC 256 WW S30 | 412471 | 24 |
| TIC/CLA -V CON 2 TLC 256 S30 (30 Test) | 412473 | 24 |
| Trim/Sulfa 1/19 TS 32 WW S30 Pack/30 | 412481 | 24 |
| Vancomycin VA 256 WW S30 | 412488 | 24 |
| VORICONAZOLE VO 32 WW S30 | 412490 | 24 |
| Ceftolozane/Tazobactam (C/T 256) | 414447 | 24 |
| Meropenem MP 32 WW B30 | 513800 | 36 |
| Vancomycin VA 256 WW F100 | 525518 | 12 |
| Amphotericin -B AP 32 WW B30 | 526300 | 60 |
| STREPTOMYCIN SM 1024 WW B30 | 526800 | 60 |
| FOSFOMYCIN FM 1024 WW B30 | 529100 | 24 |
| Nitrofurantoin NI 512 WW B30 | 530400 | 60 |
| Ertapenem ETP 32 WW B30 (30 Test) | 531600 | 36 |
| POLYMYXIN B PO 1024 WW 830 | 533400 | 60 |
| Polymyxin B PO 1024 W B100 | 533408 | 60 |
| Colistin CO 256 WW B30 | 537300 | 60 |
| COLISTIN CO 256 WW B100 | 537308 | 60 |

Decision: The MDB approved the correction of shelf life of above mentioned medical devices as tabulated in para 2 above.

5. EXPORT-PERMIT FOR THE PURPOSE OF CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.

M/s Defence Science & Technology Organization (DESTO), Islamabad has applied for export of small quantities of medical devices or accessories or components for the purpose of clinical investigations, examination, test or analysis and requested for issuance of export permit for Surgical Masks (Qty.100) to be sent to M/s Henan Mammoth, China re-confirming the results taken in PPEs Testing Lab established in DESTO.

Decision: The Board approved the permit to export Surgical Masks (Qty.100) manufactured by M/s Defence Science & Technology Organization (DESTO), Islamabad to M/s Henan Mammoth, China for the purpose of test or analysis of mask.

6. SUBMISSION OF FREE SALE CERTIFICATE OR CE MARKED DOCUMENTS BY IMPORTERS.

6.1.

The case of the K.M Enterprises, Lahore for the below medical device was considered by the MDB in its 12th meeting held 13-05-2019 and approved subject to inspection of manufacturer abroad and provision of documents as mentioned against each:-

| S.No. | Name and Address of Establishment | Manufacturer detail | Name of Medical | Brief Description | Decision of MDB |
|-------|-----------------------------------|---------------------|-----------------|-------------------|-----------------|
|-------|-----------------------------------|---------------------|-----------------|-------------------|-----------------|

| | | | | | |
|----|--|--|---|---------------------------------|--|
| | | | Device. | | |
| 1. | M/s. K.M. Enterprises, 605-D-Block, M.A. Johar Town, Lahore. (ELI-00054) | Manufacturer/ Manufacturing Site: M/s. Euromed for Medical Industries, Area No. 10, Block (i) Free Zone, Nasr City, Cairo Egypt. FSC Egypt Issue date 06-03-2018 Fee submitted: Rs. 25,000 | Euro-Ject (Disposable Syringe) 1ml, 3ml, 5ml, 10ml Class B 05 years | Sterile, single- use syringe | Approved subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. Sizes demanded on Form-7A shall be granted. Sizes not on free sale certificate. |

Decision: The Board approved the above medical device on the basis of CE marked documents.

6.2.

The case of the K.M Enterprises, Lahore for the below medical device was considered by the MDB in its 14th meeting held 11-10-2019 and decided as mentioned against each:-

| | | | | | |
|----|---|--|--|--------------|---|
| 1. | M/s. K.M. Enterprises, 605-D-Block, M.A. Johar Town, Lahore. | Legal Manufacturer: M/s. Changzhou Medical Appliances General Factor Co., Ltd., HengShangqiao Town, Changzhou Jiangsu China. FSC not found | AMD Disposable Infusion set with needle (Infusion Set) Class B Shelf Life : 05 years | Infusion Set | Approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of original notarized ISO, FQA and credentials of manufacturer. |
|----|---|--|--|--------------|---|

Decision: The Board approved the above medical device on the basis of CE marked documents.

6.3.

The case of the K.M Enterprises, Lahore for the below medical device was considered by the MDB in its 14th meeting held 11-10-2019 and decided as mentioned against each:-

| | | | | | |
|----|---|--|---|------------------------|--|
| 1. | M/s. K.M. Enterprises, 605-D-Block, M.A. Johar Town, Lahore. | Legal Manufacturer & Manufacturing Site: M/s. Changzhou Medical Appliances General Factor Co., Ltd., HengShanQian Town, | AMD Disposable Syringes 1ml, 2ml, 3ml, 5ml, 10ml, 20ml (Syringes for single use) | Disposbale Syringes | Approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Full quality Assurance. |
|----|---|--|---|------------------------|--|

| | | | | | |
|--|--|---|--|--|--|
| | | Changzhou Jiangsu China. FSC China (Export Only) Valid until 12-10-2019 | Class B Shelf Life : 05 years Rs.40,000 | | |
|--|--|---|--|--|--|

Decision: The Board approved the renewal of AMD Disposable Syringes 1ml, 10ml, 20ml only on the basis of CE marked documents.

7. EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017

M/s AGP Limited, B-23-C, SITE, Karachi has requested for exemption of labeling rules for the import of **Oneject Auto Disable Syringe 0.5ml (Regn.No.MDIR-0002118)**. The firm has started that 0.5ml syringes are generally used for immunization and will also be used to inoculate COVID-19 Vaccine (Gem-COVID-Vac). In order to ensure sufficient supplies of this syringe in Pakistan, they have requested their principals to allocate some quantity of the syringe for Pakistan on urgent basis from their existing inventory as the provision of syringes with Pakistan specific labeling will take 4-6 months due to high demand of this syringe worldwide. However, the syringes available in stocks have labels in Indonesian /English Language (Artwork are attached). Meanwhile, we have started working on the availability of syringes with Pakistan specific labeling and assure you that they will switch to Pakistan specific labeled syringes as soon as possible.

Considering the urgent requirement of these syringes in Pakistan, M/s AGP Limited, Karachi has requested for an exemption from the labeling rules of medical devices on this order of ten million (10,000,000) syringes.

Decision: The Board after detail discussion decided to accede to the request of the firm for exemption of labeling rules to the extent of writing registration number on each syringe (blister pack) but will print the registration number on outer carton of syringes for a period of six (06) months. The Board directed that the said syringes, in any case, shall not be sold in the market.

8. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES).

| S. # | Name and Addresses of Establishment | Manufacture Details | Name of Medical Device with sizes/ Class/Shelf Life | Brief Description | Decision |
|-------------|--|----------------------------|--|--------------------------|---------------------------------------|
| 1. | M/s ZamZam Pharmaceutical, | Legal Manufacturer: | Yixin Sterile Auto- | Sterile Auto-Disable | Rejected , as the same medical |

| | | | | |
|--|--|--|---|---|
| Suit No.16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi (ELI- | M/s Jiangxi SanxinMedtec Co., Ltd., No.999, Fushan Road, Xiaolan Economic Development Zone Nanchang Jiangxi, China 0.5ml & 0.1ml are WHO Prequalified | Disable Syringe for fixed dose immunization Class B Shelf Life: 05 Years Sizes: 0.5ml, 0.1ml, 1ml, 2ml, 3ml & 5ml | Syringe for fixed dose immunization | device with the same brand from the same manufacturer has already been registered in the name of M/s Usmanco International, Karachi. |
|--|--|--|---|---|

9. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

| S.# | Name of Firm (s) | Name of Manufacturer | Name of Medical Devices. | Brief Description | Decision |
|-----|--|---|---|---|---|
| 1. | M/s Diag. M (Pvt) Limited. B- 270, Sector 6-F EBM Causeway, Mehran Town, Korangi, Karachi. (ELI-00184) | Manufacturer: Biosystems, S.A., C/Costa Brava, N 30, 08030 Barcelona, Spain (FSC Spain issued on 27-04-2018) | BioSystems Glucose (reagent) Class B Shelf Life: 36 months Code: 11803, 11503, 11504, 11538, 12503, 21503, 23503 Fee submitted: Rs. 25,000/- | Reagents for the measurement of glucose concentration in human blood serum, or plasma and in human cerebrospinal fluid. | Approved. The firm shall provide valid ISO13485, letter of authorization and MRP before issuance of registration certificate. |
| 2. | -do- | Manufacturer: Biosystems, S.A., C/Costa Brava, N 30, 08030 Barcelona, Spain (FSC Spain issued on 27-04-2018) | BioSystems Creatinine (reagent) Class B Shelf Life: 36 months Code: 11802, 11502, 11542, 12502, 21502, 23502 Fee submitted: Rs. 25,000/- | Reagents for the measurement of creatinine in human serum, plasma or in human urine. | Approved. The firm shall provide valid ISO13485, letter of authorization and MRP before issuance of registration certificate. |
| 3. | M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th | Legal Manufacturer: MEDTRONIC INC., 710 | Starfish® Evo Heart Positioner Class D | A disposable, retractor-based device intended for use during | Approved. |

| | | | | | |
|----|---|--|--|--|---|
| | Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) | Medtronic Pkwy, Minneapolis, MN USA 55432. Manufacturing site Viant Medical Inc 620 Watson SW, GR, MI USA 49504 (FSC USFDA valid till 29-03-2022) | Ref: HP3000 Shelf Life: 3 Years Fee submitted: Rs. 50,000/- | coronary artery bypass grafting operations for positioning the heart. Sterile, single use. | |
| 4. | -do- | Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA Manufacturing Site: Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021) | Sensia DDDR (implantable pulse generator) [Model: SEDRL1] Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/- | Dual chamber, multiprogrammable, rate-responsive implantable pulse generator (IPG)/pacemaker indicated for use to improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or conduction disorders. Sterile, single-use | Approved. The firm shall provide valid ISO13485 and Label of the product before issuance of registration certificate. |
| 5. | -do- | Legal Manufacturer: Medtronic, INC. 8200 Coral Sea Street NE Mounds View, MN USA 55112 Manufacturing site: Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II, Bayan Lepas, Pulau | Single Chamber Temporary External Pacemaker (Model 53401) Class C Shelf Life: N/A Fee submitted: Rs. 50,000/- | Battery powered, single chamber, external pulse generator intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment | Approved. |

| | | | | | |
|----|--|---|---|---|--|
| | | Pinang Malaysia 11900 (FSC US FDA valid till 06-02- 2022) | | | |
| 6. | M/s Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi ELI: 00109 | Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany FSC Germany issued on 10-08- 2020 | Enticos 4 SR (Single Chamber Pacemaker-MR Conditional) Code: 407167 Class: D Shelf Life: 19 months Fee submitted: Rs. 50,000/- | Implantable pacemaker, MR conditional, sterile, single-use | Approved The firm shall submit original, valid and notarized Letter of Authorization, Credentials and MRP before issuance of registration certificate. |
| 7. | -do- | Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany FSC Germany issued on 10-08- 2020 | Enticos 4 D (Dual Chamber Pacemaker-MR Conditional) Code: 407156 Class: D Shelf Life: 19 months Fee submitted: Rs. 50,000/- | Implantable pacemaker, MR conditional, sterile, single-use | Approved The firm shall submit original, valid and notarized Letter of Authorization, Credentials and MRP before issuance of registration certificate |
| 8. | -do- | Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany FSC Germany issued on 10-08- 2020 | Enticos 4 S (Single Chamber Pacemaker-MR Conditional) Code: 407168 Class: D Shelf Life: 19 months Fee submitted: Rs. 50,000/- | Implantable pacemaker, MR conditional, sterile, single-use | Approved The firm shall submit original, valid and notarized Letter of Authorization, Credentials and MRP before issuance of registration certificate |

| | | | | | |
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| 9. | M/s Noor International, Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061) | Manufacturer: Radiometer Medical ApSAkandevej 21 DK-2700 Bronshoj Denmark (FSC Denmark valid till 27-06-2021) | ABL800 BASIC with Autocheck Analyzer Code: 393-844 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/- | Intended for in vitro testing of samples of expired air for the parameters pO ₂ and pCO ₂ and invitro testing of samples of whole blood for pH, pCO ₂ , pO ₂ , ctHb, sO ₂ , concentration of potassium, sodium, calcium, chloride, glucose and lactate | Approved. The firm shall provide valid ISO13485 before issuance of registration letter. |
| 10. | -do- | Legal Manufacturer: Radiometer Medical ApSAkandevej 21 DK-2700 Bronshoj Denmark Manufacturing site: SenDx Medical Inc. 1945 Palomer Oaks Way, Carlsbad, CA 92011, USA (FSC Denmark valid till 07-03-2020) | ABL80 FLEX Analyzer Code: 393-839 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/- | Portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, hematocrit in whole blood | Approved. The firm shall provide valid FSC and ISO13485 before issuance of registration letter. |
| 11. | M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030) | Legal Manufacturer: Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, CH Manufacturing site: Kimball Electronics Poland Sp. z.o.o. ul. Poznanska 1C, 62-080 | Diastix Reagent Strip (Urine Test Strip) Class B Shelf Life: 42 Months Fee submitted: Rs. 25,000/- | Intended for self-testing by persons with diabetes and by healthcare professionals to monitor the level of glucose in urine. | Deferred for provision of valid ISO13485, Full Quality Assurance Certificate and stability study supporting the claimed shelf life of 42 months. |

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| | | TarnowoPodgorne Poland (FSC Switzerland valid till 14.06.2022) | | | |
| 12. | -do- | <p>Legal Manufacturer: Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, CH</p> <p>Manufacturing site: Kimball Electronics Poland Sp. z.o.o. ul. Poznanska 1C, 62-080 Tarnowo Podgorne Poland (FSC Switzerland valid till 14.06.2022)</p> | <p>Keto-Diastix Reagent Strip (Urine Test Strip)</p> <p>Class B</p> <p>Shelf Life: 42 Months</p> <p>Fee submitted: Rs. 25,000/-</p> | Intended for self-testing by persons with diabetes and for the presence and concentration of glucose and ketone (acetoacetic acid) in urine. | <p>Approved.</p> <p>Firm shall provide valid ISO13485 and Full Quality Assurance Certificate before issuance of registration certificate.</p> |
| 13. | Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) | <p>Manufacturer: Abbott Diabetes Care Ltd. Range Road, Witney, Oxon, OX29 0YL, United Kingdom</p> <p>FSC UK MHRA issued on 05-05-2020</p> | <p>FreeStyleLibre Flash Glucose Monitoring System (Sensor Kit)</p> <p>Code: 71632-01</p> <p>Class C</p> <p>Shelf life: 18 months</p> <p>Fee submitted: Rs. 50,000/-</p> | Intended to be used together with a compatible reader or app to monitor interstitial fluid glucose levels in people with diabetes mellitus and is designed to replace blood glucose testing in the self-management of diabetes, including dosing of insulin | <p>Approved.</p> <p>Firm shall provide MRP before issuance of registration letter.</p> |
| 14. | -do- | <p>Manufacturer: Abbott Diabetes Care Ltd. Range Road, Witney, Oxon,</p> | <p>FreeStyleLibre Flash Glucose Monitoring System (Reader Kit)</p> | Intended to be used together with a compatible sensor to monitor interstitial fluid | <p>Approved.</p> <p>Firm shall provide MRP before issuance</p> |

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| | | OX29 OYL, United Kingdom FSC UK MHRA issued on 05-05- 2020 | Code: 71620-01 Class C Shelf life: N/A Fee submitted: Rs. 50,000/-Codes & Sizes as per FSC | glucose levels in people with diabetes mellitus and is resigned to replace blood glucose testing in the self- management of diabetes, including dosing of insulin | of registration letter. |
| 15. | -do- | Manufacturer: M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China FSC Germany valid till 25.05.2022 | HIV 1/2/0 Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plas ma) Class D Code: IHI-T402 Shelf life: 24 Months Fee submitted: Rs. 50,000/- | Rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1, HIV-2, and subtype O in whole blood, serum, or plasma to aid in diagnosis of HIV infection | Approved. Firm shall provide valid Full QA Certificate before issuance of registration letter. |
| 16. | -do- | Legal Manufacturer: B.R.A.H.M.S GmbH, NeuendorfstraBe 25, 16761, Henningsdorf, Germany Manufacturing site: Microgenics Corporation 46500 Kato Road, Fremont, California, 94538 USA FSC Germany issued on 17-10- 2018. | Alinity c Phenobarbital Reagent Kit Class C Code: 09P8520 Shelf life: 7 months Fee submitted: Rs.50,000/- | Intended for the quantitative measurement of phenobarbital in human serum or plasma on the Alinity c analyzer. | Approved. Firm shall provide MRP before issuance of registration letter. |

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| 17. | -do- | <p>Manufacturer: M/s Sekisui Medical Co. Ltd., 1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan</p> <p>FSC UK Issued on 11-05-2017</p> | <p>Coagpia® α_2-PI Test Kit</p> <p>Coagpia® α_2-PI Reagent Shelf life: 2 years Code: 03R46-20</p> <p>Coagpia Calibrator Shelf life: 2 years Code: 02R84-01</p> <p>Coagpia Control Set Shelf life: 2 years Code: 02R85-10</p> <p>Class C</p> <p>Fee submitted: Rs. 50,000/-</p> | <p>Intended for the quantitative determination of α_2-plasma inhibitor activity in human citrated plasma. The reagent is intended for use on Sekisui coagulation analyzers</p> | <p>Approved.</p> <p>Firm shall provide MRP before issuance of registration letter.</p> |
| 18. | -do- | <p>Legal Manufacturer: M/s Sekisui Diagnostics (UK) Ltd. Liphook Way AllingtonMaidstone Kent ME16 0LQ, UK. Manufacturing Site: M/s Sekisui Medical company Ltd., 13-5, Nihonbashi 3-chome, chou-ku, Tokyo, 103-0027, Japan. (Both are sister companies)</p> | <p>COAGPIA APTT FS Reagent (LN04S86-20), Coagpia Control Set (LN02RS85-10).</p> <p>Codes & Sizes as per FSC Claimed Shelf-life: 24months. Class:C. FSC UK Issuance Date (11-05-2017).</p> | <p>Coagpia APTT FS Reagent, Coagpia Control Set.</p> | <p>Approved.</p> <p>Firm shall provide valid ISO.13485 duly notarized by the country of origin, distribution agreement and MRP before issuance of registration certificate.</p> |
| 19. | -do- | <p>Legal Manufacturer: M/s BRAHMS GmbH, NeuendorfstraBe 25, 16761 Hennigsdorf, Germany. Production Site: • Microgenics</p> | <p>ALINITY c Theophylline Reagent Kit</p> <p>Claimed Shelf-life: 07-months. Class: C. FSC Germany Issuance Date (17-10-2018).</p> | <p>Alinity c Theophylline Reagent Kit.</p> | <p>Approved.</p> <p>Firm shall provide MRP before issuance of registration certificate.</p> |

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| | | Corps. 46500 Kato Road Fremont, CA, USA. | | | |
| 20. | -do- | Legal Manufacturer: M/s Sekisui Diagnostics (UK) Ltd. Liphook Way AllingtonMaidston e Kent ME16 0LQ, UK. Manufacturing Site: M/s Sekisui Medical company Ltd., 13-5, Nihonbashi 3- chome, chou-ku, Tokyo, 103-0027, Japan. (Both are sister companies) | COAGPIA PC Reagent (LN03R45-20), Calibrator (LN02R84-01), Control Set (LN02R85-10), Claimed Shelf-life: 24months. Class:C. FSC UK Issuance Date (11-05-2017). | Coagpia PC Reagent Coagpia Calibrator Coagpia Control Set. | Approved. Firm shall provide valid ISO.13485 duly notarized by the country of origin, distribution agreement and MRP before issuance of registration certificate. |
| 21. | -do- | Legal Manufacturer: M/s Sekisui Diagnostics (UK) Ltd. Liphook Way AllingtonMaidston e Kent ME16 0LQ, UK. Manufacturing Site: M/s Sekisui Medical company Ltd., 13-5, Nihonbashi 3- chome, chou-ku, Tokyo, 103-0027, Japan. (Both are sister companies) | COAGPIA Heparin Reagent (LN03R48-20), Calibrator (LN03R48-01), Control Set (LN03R48-10). Claimed Shelf-life: 24months. Class:C. FSC UK Issuance Date (11-05-2017). | Coagpia Heparin Reagent Coagpia Heparin Calibrator Set Coagpia Heparin Control Set. | Approved. Firm shall provide valid ISO.13485 duly notarized by the country of origin, distribution agreement and MRP before issuance of registration certificate. |
| 22. | -do- | Legal Manufacturer: M/s Alere Technologies GmbH LoebstedterStrasse 103-105 07749 Jena, Germany. | m-PIMA HIV-1/2 VL Cartridge System. (Ref:270150050) Claimed Shelf-life: 10-months. Class:C. FSC Germany | FOR HIV type 1 and 2 diagnostics (a viral load load monitoring system). | Approved. Firm shall provide MRP before issuance of registration certificate. |

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| | | | Issuance Date (25-01-2019) | | |
| 23. | -do- | Legal Manufacturer: M/s BRAHMS GmbH, NeuendorfstraBe 25, 16761 Hennigsdorf, Germany. Production Site: Microgenics Corps. 46500 Kato Road Fremont, CA, USA. | ALINITY c Valproic Acid Reagent Kit Claimed Shelf-life: 07-months. Class: C. FSC Germany Issuance Date (17-10-2018). | Alinity c Valproic Acid Reagent Kit. | Approved. Firm shall provide MRP before issuance of registration certificate. |
| 24. | -do- | Legal Manufacturer: M/s BIOKIT, S.A. Can Male S/N 08186 LLICA D Amunt (Barcelona) Spain. FSC Spain Issuance Date (21-05-2019) | QUANTIA D-Dimer (7K02-02), Control (7K02-21) & Standard (7K02-11). Claimed Shelf-life: 24-months. Class: C. | Quantia D-Dimer. | Deferred for provision of original fee slip or importer's copy and MRP. |
| 25. | -do- | Legal Manufacturer: M/s Sekisui Diagnostics (UK) Ltd. Liphook Way AllingtonMaidstone Kent ME16 0LQ, UK. Manufacturing Site: M/s Sekisui Medical company Ltd., 13-5, Nihonbashi 3-chome, chou-ku, Tokyo, 103-0027, Japan. (Both are sister companies) | COAGPIA PLG Reagent (LN03R47-20) Calibrator (LN02R84-01) Control Set (LN02R85-10). Claimed Shelf-life: 24-months. Class: C. FSC UK Issuance Date (11-05-2017). | COAGPIA PLG Reagent. | Approved. Firm shall provide valid ISO 13485 duly notarized by the country of origin, distribution agreement and MRP before issuance of registration certificate. |
| 26. | -do- | Legal Manufacturer: M/s BIOKIT, S.A. Can Male S/N 08186 LLICA D | QUANTIA RF(6K44-02) RF Standard (6K52-03) QUANTIA ASO | Quantia Rheumatoid Factor and ASO TITRE diagnostic kit. | Approved. Firm shall provide MRP before issuance |

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| | | Amunt (Barcelona) Spain. FSC Spain Issuance Date (24-01-2019) | (6K38-02) ASO Standard (6K46-03) Quantia ASO-RF Control I (6K54-02) Quantia ASO-RF Control II (6K55-02) Shelf-life: RF: 13- months. ASO: 19-months. Class: B. | | of registration certificate. |
| 27. | -do- | Legal Manufacturer: M/s BIOKIT, S.A. Can Male S/N 08186 LLICA D Amunt (Barcelona) Spain. FSC Spain Issuance Date (24-01-2019) | ALINITY c Lp(a) Reagent (1R14-20), Calibrator (1R14-01) & Control (1R14-10). Claimed Shelf-life: 09-months. Class: B. | ALINITY c Lp(a) Reagent IVD-Kit. | Approved. Firm shall provide MRP before issuance of registration certificate. |
| 28. | -do- | Legal Manufacturer: M/s BIOKIT, S.A. Can Male S/N 08186 LLICA D Amunt (Barcelona) Spain. | QUANTIA IgE Reagent (6K42-02), Standard (6K50-03) & Control (6K56-02). Claimed Shelf-life: 23-months. Class: B. FSC Spain Issuance Date (24-01-2019) | QUANTIA IgE Reagent (6K42-02), Standard (6K50-03) & Control IVD-Kit. | Approved. Firm shall provide MRP before issuance of registration certificate. |
| 29. | -do- | Legal Manufacturer: M/s BIOKIT, S.A. Can Male S/N 08186 LLICA D Amunt (Barcelona) Spain. FSC Spain Issuance Date (21-05-2019) | QUANTIA Myoglobin Reagent (6L32-43), Standard (6L33-05) & Control (6K56-02). Claimed Shelf-life: 18-months. Class: B. FSC Spain Issuance Date (24-01-2019) | QUANTIA Myoglobin Reagent, Standard & Control IVD-Kit. | Deferred for provision of original fee slip or importer's copy and MRP. |

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| 30. | -do- | <p>Manufacturer: Microgenics Corporation 46500 Kato Road, Fremont, California, 94538 USA</p> <p>FSC US FDA valid till 06-11-2020</p> | <p>Carbamazepine (Kit) Class C Code: 5P05-21 Shelf life: 18 months Fee submitted: Rs. 50,000/- (Challan No. 0580472)</p> | <p>Used for the in vitro quantitative measurement of carbamazepine in human serum or plasma on the ARCHITECT c systems.</p> | <p>Approved. Firm shall provide valid FSC and MRP before issuance of registration letter.</p> |
| 31. | -do- | <p>Manufacturer: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.</p> <p>(FSC Germany issued on 24.05.2019)</p> | <p>Panbio Dengue Duo Cassette Class C Code: 01PF10 Shelf Life: 18 Months Fee Submitted: Rs.50,000/-</p> | <p>For the qualitative detection of IgM and IgG antibodies to dengue serotypes (1,2,3,4) in human serum, plasma and whole blood</p> | <p>Approved. Firm shall provide valid ISO 13485 and MRP before issuance of registration letter.</p> |
| 32. | <p>M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)</p> | <p>Legal Manufacturer: Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium Manufacturing Sites: 1. Johnson and Johnson Medical GmbH, Robert-Koch-Strasse 1, Norderstedt, 22851, Germany 2. Johnson and Johnson Medical Limited, Simpson Parkway, Kirkton, Campus,</p> | <p>Coated Vicryl™Plus Antibacterial Suture. Class D Codes: VCP247H VCP300H VCP3100H VCP3110H VCP320H VCP360H VCP9213H VCP310H FSCs does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them.</p> | <p>A synthetic absorbable sterile surgical suture composed of a copolymer made from 90 % glycolide and 10 % L-lactide. Intended for use in general soft tissue approximation and/or ligation including microsurgery for vessels than 2mm diameter. Single-use</p> | <p>Approved. The firm shall provide valid ISO13485 before issuance of registration letter.</p> |

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| | | Livingston, Scotland, EH54 7AT, United Kingdom (FSC Belgium issued on 03-05- 2019) (FSC UK issued on 24-02-2016) | Shelf Life: 36 Months Fee submitted: Rs. 50,000/- | | |
| 33. | M/s Claris Medical, Unit No. 27, 3 rd floor. Twin City Plaza, I-8 Markaz, Islamabad. ELI: 00269 | Manufacturer: M/s Quest Medical, Inc. One Allentown Parkway Allen, Tx 75002-4211, USA FSC, USFDA valid till 15-03- 2022 | MPS Delivery Set (Cardioplegia Delivery Set) Class D Shelf Life: 3 years Codes: 5001102, 5001102AS, 5161102 Fee submitted: Rs. 50,000/- | For delivery of cardioplegia solutions to the heart during cardiopulmonary bypass surgery. Sterile, single-use | Approved The firm shall submit Embassy attested FSC and Credential before issuance of registration letter. |
| 34. | M/s. Haji S. Ameer Din & Sons, 305-A, Upper Mall, Lahore. ELI-00059 | Manufacturer: UNICOS Co. Ltd 282-30, Munji-ro, Yuseong-gu, Daejeon, Korea FSC Korea issued on 08.04.2019 | Unicos Auto Refracto- Keratometer URK- 900F (Ophthalmic refractometer) Class: B Life Time: 20,000H Fee submitted: Rs. 25,000/- | Used to determine the initial, objective refractive values for a patient 's eye in the workflow of refraction to determine the optical prescriptions for myopia, hyperopia and astigmatism. | Deferred for provision of FSC from a reference country Other models to be applied separately |
| 35. | M/s Hooraa Pharma (Pvt) Ltd., WH-01-20- A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037) | Legal Manufacturer/ Manufacturing Site: M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, UK | IMMULITE 2000 Rubella IgM Assay Kit Class C IMMULITE 2000 Rubella IgM Ref: L2KRM2 Shelf Life: 12 Months | For the qualitative detection of IgM antibodies to rubella virus in human serum or plasma as an aid in the presumptive diagnosis of acute or recent rubella infection, particularly in | Approved. |

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| | | (FSC Ireland Valid Till 11-09-2024) | IMMULITE 2000 Rubella IgG/IgM Sample Diluent Ref: L2IGZ2 Shelf Life: 3 years Fee submitted: Rs. 50,000/- | women of child bearing age. | |
| 36. | -do- | Legal Manufacturer/ Manufacturing Site: M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, UK (FSC Ireland Valid Till 11-09-2024) | IMMULITE 2000 Rubella IgG Assay Kit Class C IMMULITE 2000 Rubella Quantitative IgG Ref: L2KRUB2 Shelf Life: 12 Months IMMULITE 2000 Rubella Quantitative IgG Ref: L2KRUB6 Shelf Life: 12 months Fee submitted: Rs. 50,000/- | For the quantitative measurement of IgG antibodies to rubella virus in human serum as an aid in the determination of immune status to rubella, particularly in women of child bearing age. | Approved. |
| 37. | M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 | Legal Manufacturer: M/s Dragerwerk AG &CO, KGaA Moisinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: Dragerwerk AG & Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. FSC: Germany Date of issue: 15.10.19 | Drager O2STAR Venturi Mask (Disposable O2 therapy accessories) Class-B Shelf Life: 3 Years Codes: Adjustable (S, M/L) Fixed (S, M/L) | Disposable O2 therapy accessories | Approved. |

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| 38. | -do- | <p>Legal Manufacturer: M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany</p> <p>Manufacturing Site: Dragerwerk AG & Co. KGaA RevalstrBe 1 23560, Lubeck, Germany.</p> <p>FSC: Germany Date of issue: 15.10.19</p> | <p>Drager Spirolog (Flow Sensor)</p> <p>Class-B</p> <p>Shelf Life: Sensor is subjected to wear and tear and can be used as long as successful calibration is possible.</p> <p>Codes: Spirolog Flow Sensor (5x)</p> | <p>The flow sensor is a hot-wire sensor for measuring volumetric gas flow in Drager synesthesia machines and ventilators.</p> | Approved. |
| 39. | M/s Renacon Pharma Limited. | <p>Legal Manufacturer: M/s Jiangxi Sanxin Medtec Co., Ltd, No. 999 Fushan Road, Xiaoln Economic Development Zone, Nanchang, Jiangxi, 330200, P.R. China.</p> <p>FSC China validity 18-10-2022</p> | <p>Rena-Line Blood Tubing Line.</p> <p>Class-B</p> <p>Shelf Life: 2 Years</p> <p>Codes as per FSC</p> | <p>Blood tubing line for hemodialysis</p> | Approved on the basis of CE marked documents. |
| 40. | Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi, 75300 Pakistan | <p>Legal Manufacturer: Farcomake For Advanced Medical Industries (S.A.E) Borg Al-Arab, 4th Industrial Zone, Block-2, Part 7/16 Alexandria Egypt.</p> <p>FSC Egypt validity till April 2023</p> <p>FSC Germany issuance 12-2020</p> | <p>INPHARVEN I.V. Cannula</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G</p> | <p>IV Cannula</p> | Approved. |

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| 41. | M/s. Amin Agencies, CB-6349/B, Amar pak Plaza, Jhelum Road, Rawalpindi ELI-00610 | Legal Manufacturer: CONIC VASCULAR TECHNOLOGY, S.A VIA CARLO MADERNO, 23 CH. 6901 LUGANO, SWITZERLAND. Manufacturer Site: Conic Vascular Espana, S.L C/ Entrerrios, n 9 bajo 15220 Ames Spain FSC Switzerland Valid till: 11.06.2022 | NC Clever PTCA BALLOON CATHETER (NON-COMPLIANT) Class D Shelf Life:2.5 years Codes & sizes as per FSC | Indicated by the physician in patients with significant coronary artery disease | Approved. |
| 42. | M/s Ghazali Brothers, 1st Floor, Azzainab Court Compbell Street, Karachi (ELI-00240) | Legal Manufacturer: M/s Ningbo Yingmed Medical Instruments Co., Ltd., Room 705, Yingsheng Building No.456 Tai'an RD, Southern Business Zone, Yinzhou District, 315199 Ningbo, P.R. China. (FSC UK Issuance 09-02-2018) | Yingmed Disposable Needle, Sterile Class B Shelf Life: 5 Years (Sizes & Codes as Per FSC) 30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G | Disposable Needle is Composed by cap, needle tube and hub. The raw material of cap and hub is PP; and of needle tube is SUS304. | Approved. |
| 43. | -do- | Legal Manufacturer: M/s Ningbo Yingmed Medical Instruments Co., Ltd., Room 705, Yingsheng Building No.456 Tai'an RD, Southern Business Zone, Yinzhou | Yingmed Disposable Surgical Blade, Sterile Class B Shelf Life: 5 Years Model/Sizes as per FSC | Disposable Surgical Blades and Scalpel with plastic handle jointed by surgical blade and ABSs engineering plastic handle are basic surgical devices | Approved. |

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| | | District, 315199 Ningbo, P.R. China. FSC UK Issuance (09-02-2018) | | | |
| 44. | M/s. Global Health Care, Midway Commercial Plaza No. 20, BackSide of prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. (ELI-00086) | Legal Manufacturer: Troge Medical Milchstrasse 19,20148 Hamburg Germany FSC: Germany Date of issue 17.08.2018 | (Trojector-U 100) (Insulin syring with integrated needle) Class: B Shelf Life 5 years Codes & sizes as per FSC | This is 03-part syringe consists of a cylinder and an inner piston with a double sealing rubber gasket. It is sterile and pyrogen free and made of a toxic polypropylene and polyethylene material. | Approved. |
| 45. | M/s Shazoo SPL Consumer Healthcare, 71 B/C2, Gulbert 3, Lahore ELI: 00095 | Legal Manufacturer: Aesthetic Group Z.a La Gobette 60540 Puisieux Le Hauberger France FSC: France Date of Issue: 03.01.2019 | Flexible Micro Cannula Micro cannula for filler injection with KR hub Class-B Shelf life: 3 years Code: as per FSC | The flexible micro cannulas are used to inject a filler under the skin | Approved. Firm shall provide Labels before issuance of registration certificate. |
| 46. | M/s Intra Health, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00049) | Legal Manufacturer: Kawa Medical products Co.,Ltd. No. 2 Xiangan Road, ShouguangBeiluo Industrial Park, Weifang, Shandong China. FSC China valid till 02-11-2021 (FSC Germany issuance 11-02-2019) | Kawa 3-way stopcock Class B Shelf Life: 5 Years Sizes & Codes as Per FSC STC-101, STC-102 STC-103, STC-104 STC-105, STC-106 STC-201, STC-401 STC-301 | Products is intended for infusions | Approved as class A device. |
| 47. | -do- | Legal Manufacturer: Kawa Medical | Kawa Unibody Insulin syringe | The product is intended for injections and are | Approved. |

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| | (Renewal) | products Co.,Ltd. No. 2 Xiangan Road, ShouguangBeiluo Industrial Park, Weifang, Shandong China. FSC China valid till 02-11-2021 (FSC Germany issuance 11-02-2019) | Class B Shelf Life: 5 years Sizes & Codes as Per FSC 1cc | made of molded components | |
| 48. | -do- | Legal Manufacturer: Kawa Medical products Co.,Ltd. No. 2 Xiangan Road, ShouguangBeiluo Industrial Park, Weifang, Shandong China. FSC China valid till 02-11-2021 (FSC Germany issuance 11-02-2019) | Kawa Redon wound drain system Class B Shelf Life: 5 year Sizes & Codes as Per FSC Bottles with tubes RWS-01, RWS-02 | Products is intended for infusions | Approved. |
| 49. | -do- | Legal Manufacturer: Kawa Medical products Co.,Ltd. No. 2 Xiangan Road, ShouguangBeiluo Industrial Park, Weifang, Shandong China. FSC China valid till 02-11-2021 (FSC Germany issuance 11-02-2019) | Kawa IV Catheters Class B Shelf Life: 5 year Sizes & Codes as Per FSC IVC-01 | Products is intended for infusions | Approved. |
| 50. | -do- | Legal Manufacturer: Kawa Medical | Kawa IV Flow Regulator | Products is intended for infusions | Approved. |

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| | | <p>products Co.,Ltd. No. 2 Xiangan Road, ShouguangBeiluo Industrial Park, Weifang, Shandong China.</p> <p>FSC China valid till 02-11-2021 (FSC Germany issuance 11-02-2019)</p> | <p>Class B Shelf Life: 5 year</p> <p>Sizes & Codes as Per FSC 10-5 Double scale</p> | | |
| 51. | -do- (Renewal) | <p>Legal Manufacturer: Kawa Medical products Co.,Ltd. No. 2 Xiangan Road, ShouguangBeiluo Industrial Park, Weifang, Shandong China.</p> <p>FSC China valid till 02-11-2021 (FSC Germany issuance 11-02-2019)</p> | <p>Unison Intravenous Volume Control Set with Burette 100 ml</p> <p>Class B Shelf Life: 5 Years Sizes & Codes as Per FSC Intravenous Volume Control Set with Burette 100 ml</p> | Device is intended for the delivery of Infusion | Approved. |
| 52. | M/s Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi. (ELI-00347) | <p>Legal Manufacturer: Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Bershire, RG6 4UT, United Kingdom.</p> <p>(FSC Valid 07-03-2023)</p> | <p>Lorne Blood Grouping Reagents (Rhesus System-Monoclonal Reagent)</p> <p>Class D</p> <p>Shelf Life: Reagents: 750002, 690005, 691005, 692005, 693005, 700010 (24M) 710010, 730010, 740010 (30M) Controls: 640010, 209005,</p> | Blood Grouping Reagents (Rhesus System-Monoclonal Reagent) | Approved. |

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| | | | <p>427002, 401010, 402010, 415010, 435010 (24M) 650010 (30M) Buffers: 470020, 470250, 470025, 480010, 485010 (12M)</p> <p>Sizes & Codes as Per FSC Reagents: 750002, 690005, 691005, 692005, 693005, 700010, 710010, 730010, 740010 Controls: 640010, 650010, 209005, 427002, 401010, 402010, 415010, 435010 Buffers: 470020, 470250, 470025, 480010, 485010</p> | | |
| 53. | -do- | <p>Legal Manufacturer: Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Berkshire, RG6 4UT, United Kingdom. (FSC Valid 07-03-2023)</p> | <p>Lorne Kidd System of Blood Group (Blood Group Reagents for Rare Blood groups) Class D Shelf Life: 24 Months Codes: 775002 (Anti-Jka) 776002 (Anti-Jkb)</p> | Kidd System of Blood Group (Blood Group Reagents for Rare Blood groups) | Approved. |
| 54. | -do- | <p>Legal Manufacturer: Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower</p> | <p>Lorne Grouping Reagents for M, N and S group System Class D Shelf Life: 24</p> | Grouping Reagents for M, N and Systems | Approved. |

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| | | Earley, Reading, Bershire, RG6 4UT, United Kingdom. (FSC Valid 07-03-2023) | Months Sizes & Codes as Per FSC Reagents: 311022, 312002, 770002, 771002 Controls: 401010, 402010, 415010, 435010 | | |
| 55. | M/s. Iqbal & Company AlfalahManzilOpp: National Police Foundation, Street No.26, Sector E-11/4, Islamabad. ELI-00117 | Manufacturer M/s. Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121, USA FSC: Germany Issuance: 30/11/2017 | Hemochron® Celite ACT Tubes Act (Activated clotting time) Tubes Class: B Shelf Life 3 Years Code: HRFTCA510 | The Hemochron® Celite ACT Tube is commonly used for Heparin anticoagulation monitoring during cardiopulmonary bypass surgery, percutaneous transluminal coronary angioplasty (PTCA), Interventional radiology, extracorporeal membrane oxygenation (ECMO), Hemofiltration, hemodialysis and critical care. The various ACT tests are intended solely for use with Hemochron Response Models. | Approved. |
| 56. | -do- | Manufacturer: SUNDER BIOMEDICAL TECH. CO. LTD No. 16. Chung-Chen Rd., Chung – Ming Village, Pao-Chung Hsiang, Yunlin County, Taiwan R.O.C | SUNDER Hemodialysis Blood tubing set Codes: as per FSC Class B Shelf Life: 3 years Fee submitted: Rs. | Blood Tubing set for hemodialysis. Sterile, single-use | Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs. |

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| | | FSC Taiwan 25-04-2019 FSC Ireland valid till 13-07-2021 | 25000/- | | |
| 57. | -do- | Manufacturer: SUNDER BIOMEDICAL TECH. CO. LTD No. 16. Chung-Chen Rd., Chung – Ming Village, Pao-Chung Hsiang, Yunlin County, Taiwan R.O.C FSC Taiwan 29-04-2019 FSC Ireland valid till 13-07-2021 | SUNDER A.V Fistula Needle Set Codes: as per FSC Class B Shelf Life: 3 years Fee submitted: Rs. 25000/- | A.V Fistula Needle Set used during hemodialysis. Sterile, single-use | Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs. |
| 58. | M/s Innovate Medical Technologies, Plot No. A-7/2, Block 13/D3 Gulshan E- Iqbal, Karachi. (ELI-00352) | Legal Manufacturer: DeRoyal Industries Inc. 200 DeBusk Lane Powell. Tennessee 37849 USA. Manufacturing site: Zhejiang Longterm Medical Technology Co., Ltd No. 493 North Huancheng Road, Mogan Mountain National High-tech District Deqing, Zhejiang China 313200. FSC US FDA validity 09-01-2021. | Kalginate Dressing Calcium Alginate wound Dressing Class-C Shelf Life: 3 Years (Sizes & Codes as Per FSC) 46-900 46-901 46-902 46-903 | Alginate wound dressing is a highly absorbent dressings, which are also biodegradable because it uses substances derived from natural sources. An alginate wound dressing contains sodium and calcium derived from seaweed and come in the form of flat dressings. | Approved. Firm shall provide valid FSC before issuance of registraion ceertificate. |
| 59. | Grace Pharmaceuticals, Office No. 503, 5th Floor, Plot No. 42C/2, Lane No.8, Bukhari | Legal Manufacturer: M/s Jiangxi Hongda Medical Equipment Group Ltd., No.39 South | Alpha Urine Bag Class-B Shelf life: 5 years | Urine bag | Approved as Class A medical device. |

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| | Commercial, DHA Phase-6, Karachi (ELI-00254) | Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China <u>FSC China Valid Till 26-11-2021</u> | models: 1000ml, 2000ml | | |
| 60. | -do- | Legal Manufacturer: M/s Jiangxi Hongda Medical Equipment Group Ltd., No.39 South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China FSC China Valid Till 26-11-2021 | Alpha Hypodermic Needle Class-B Shelf life: Codes & Sizes as per FSC | Hypodermic needle | Approved subject to provision of FSC of reference country or CE mark documents. |
| 61. | M/s Mars Enterprises, Office No.4, Jason Centre, 2 nd Floor, BC-8, Block No.9, Clifton, Karachi (ELI-00097) | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany 12-12-2019 | i care disposable sterile blood transfusion set for single use Class B Shelf Life: 5 Years Sizes & Codes as Per FSC | The propose device is plastic, disposable and sterile blood transfusion set, which is intended to be used to administer blood from the container to a patient's vascular system through a needle or catheter inserted into a vein via gravity method. | Approved. |
| 62. | -do- | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China | i Care Sterile Disposable Infusion Set for single use Class B Shelf Life: 5 Years Sizes & Codes as | A Collection of sterile devices designed to conduct fluids from an intravenous (IV) Fluid container to a patient's venous system used for gravitational | Approved. |

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| | | validity 26-06-2020) FSC Germany 12-12-2019 | Per FSC | intravenous administration. | |
| 63. | -do- | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany 12-12-2019 | I care Sterile insulin syringes for single use Class B Shelf Life: 5 Years Sizes & Codes as Per FSC 0.5ml, 1ml | Plastic syringe designed for subcutaneous injection of a desire dose of insulin. | Approved. |
| 64. | -do- | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany 12-12-2019 | I care Disposable Sterile syringe for single use Class B Shelf Life: 5 Years Sizes & Codes as Per FSC (1ml, 10ml, 20ml) | A Medical Device that is used to inject fluid into, or withdraw fluid from, the body. A medical syringe consists of a needle attached to a hollow cylinder that is fitted with a sliding plunger | Approved only 1ml, 10ml and 20ml. |
| 65. | -do- | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany | I care Disposable Sterile infusion Enteral Giving Sets for single use Class B Shelf Life: 5 Years Sizes & Codes as Per FSC | The Infusion enteral giving set is mainly used for transporting nutrient solutions and food in human intestine after matching with stomach and esophagus. | Approved. |

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| | | 12-12-2019 | | | |
| 66. | -do- | <p>Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.</p> <p>(FSC China validity 26-06-2020)</p> <p>FSC Germany 12-12-2019</p> | <p>I care Disposable Sterile Hypodermic Needles for single Use (All guage)</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC</p> | <p>A hypodermic needle is a hollow needle commonly use with a syringe to inject substances into the body or extract fluids from it.</p> | Approved. |
| 67. | -do- | <p>Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.</p> <p>(FSC China validity 26-06-2020)</p> <p>FSC Germany 12-12-2019</p> | <p>I care Disposable Sterile intravenous Needle for single use (with wings)</p> | <p>The administration of intravenous therapy shall be carried out by authorized personnel in a safe, standardized manner.</p> | Approved. |
| 68. | -do- | <p>Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.</p> <p>(FSC China validity 26-06-2020)</p> <p>FSC Germany 12-12-2019</p> | <p>I care Disposable Sterile Connecting Extension Tubes for Single use</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC</p> | <p>Extension Set with Needles Connector are intravascular extension sets intended for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion continuous infusion or aspiration of</p> | Approved. |

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| | | | | drugs | |
| 69. | -do- | <p>Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.</p> <p>(FSC China validity 26-06-2020)</p> <p>FSC Germany 12-12-2019</p> | <p>I care Disposable Sterile infusion set with burette Chamber for single use</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC 80 ml, 100ml, or 150ml</p> | <p>Burette shall include a tube with spike and roller clamp at proximal end, a clamp and rotating leuer lock at the distal end, graduated burette with transparent flexible drip chamber in the center and protective caps designed to maintain sterility of the internal parts of the set until used.</p> | Approved. |
| 70. | -do- | <p>Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.</p> <p>(FSC China validity 26-06-2020)</p> <p>FSC Germany 12-12-2019</p> | <p>I care Disposable Sterile Three-way stopcocks for single (With or Without extension tube)</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC</p> | <p>Lipid resistant 3-way stopcock with one male luer-lock and two female Luer lock ends.</p> | Approved as Class A medical device. |
| 71. | -do- | <p>Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.</p> <p>(FSC China validity</p> | <p>I care Disposable Sterile Scalp Vein Set for single Use</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC 14g, 15g, 16g, 17g, 18g, 19g, 20g, 21g, 22g, 23g, 24g, 25g,</p> | <p>Scalp vein set with safety Device is intended to be used for insertion into a patient vascular system for single use as an indur device to administer fluids intravenously or</p> | Approved. |

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| | | 26-06-2020) FSC Germany 12-12-2019 | 26g, 27g, 28g, 29g, 30g, | to sample blood. | |
| 72. | -do- | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany 12-12-2019 | I care Disposable sterile syringe for single use Class B Shelf Life: 5 Years Sizes & Codes as Per FSC 30ml, 50ml, 60ml, 100ml | A medical Device that is used to inject fluids into, or withdraw fluids from the body. A medical syringe consists of a needle attached to a hollow cylinder that is fitted with a sliding plunger. | Approved. |
| 73. | -do- | Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany 12-12-2019 | I care Disposable Sterile Irrigating and Feeding Syringes for Single Use Class B Shelf Life: 5 Year Sizes & Codes as Per FSC (5ml, 10ml, 20ml, 50ml, 60ml, 100ml, 150ml, 200ml, 250ml, 300ml, 350ml, 500ml) | Irrigation syringes features variety of tops and tips to aid in the irrigation of feeding tubes and medicine dispensation. | Approved. |
| 74. | M/S Verizon. 60- D, F.C.C, ZahoorElahi Road, Gulberg- IV, Lahore. ELI-00087 | Manufacturer: M/s William Cook Europe ApS. Sandet 6DK-4632 Bjæverskov Denmark FSC Denmark valid till June 02, 2020 | MReye® Flipper® PDA Closure Detachable Coil Class D Codes: IMWCE-3-PDA3 IMWCE-3-PDA4 IMWCE-3-PDA5 IMWCE-5-PDA3 IMWCE-5-PDA4 IMWCE-5-PDA5 | Coil made from Inconel material with synthetic fibers intended for Patent Ductus Arteriosus (PDA) closure. Sterile, single-use | Approved The firm shall submit valid Letter of Authorization and FSC before issuance of registration letter. Delivery |

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| | | | <p>IMWCE-6.5-PDA3 IMWCE-6.5-PDA4 IMWCE-6.5-PDA5 IMWCE-8-PDA3 IMWCE-8-PDA4 IMWCE-8-PDA5</p> <p>Shelf Life: 5 years</p> <p>Fee submitted: Rs. 50,000/-</p> | | <p>system to be applied separately.</p> |
| 75. | -do- | <p>Manufacturer: M/s William Cook Europe ApS. Sandet 6 DK-4632 Bjaeverskov Denmark</p> <p>FSC Denmark valid till June 02, 2020</p> | <p>Hilal Embolization Microcoils™(Soft Platinum)</p> <p>Codes: Codes as per FSC Denmark dated 17-07-2019</p> <p>Class D Shelf Life: 5 years</p> <p>Fee submitted: Rs. 50,000/-</p> | <p>The microcoils made of soft platinum with synthetic fibers designed to be used for arterial and venous embolization. Sterile, single-use</p> | <p>Approved</p> <p>The firm shall submit valid Letter of Authorization and FSC before issuance of registration letter.</p> |
| 76. | M/s Meditec Instruments Co., Suit No. 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi (ELI-00233) | <p>Manufacturer: M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730.</p> <p>FSC US FDA valid till 09-01-2021</p> | <p>EasyStat Electrodes (Cluster)</p> <p>Class B</p> <p>Codes: 7205, 7206, 7207, 7208, 6201, 6202, 6203, 6204</p> <p>Shelf Life: 12 Months</p> <p>Fee submitted: Rs. 25,000/-</p> | <p>Electrolyte Electrodes to be used with EasyStat analyzer</p> | <p>Deferred for provision of valid FSC.</p> |
| 77. | -do- | <p>Manufacturer: M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730.</p> <p>FSC US FDA valid till 09-01-</p> | <p>EasyStat Reagent Module and Quality Control (Cluster)</p> <p>EasyStat Reagent Module Shelf life: 12 months</p> | <p>Electrolyte reagent and control to be used with EasyStat analyzer</p> | <p>Deferred for provision of valid FSC and COA or QC tests.</p> |

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| | | 2021 | Code:7101 BI Level Hematocrit Quality Control Shelf life: 60 months Code:7309 Fee submitted: Rs. 25,000/- | | |
| 78. | -do- | Manufacturer: M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730. FSC US FDA valid till 19-06- 2021 | EasyBloodGas Reagent Module and Quality Control (Cluster) EasyBloodGas Reagent Module Shelf life: 12 months Code: 6101 Easy QC Level 1 Blood Gas and Electrolyte Quality Control Shelf life: 36 months Code:6303 Easy QC Level 2 Blood Gas and Electrolyte Quality Control Shelf life: 36 months Code:6304 Easy QC Level 3 Blood Gas and Electrolyte Quality Control Shelf life: 36 months Code:6305 | Electrolyte reagent and control to be used with EasyBlood Gas analyzer | Approved. Firm shall provide COA or QC test before issuance of registration certificate. |
| 79. | Medco Health Care 155, C.P. Barar Society, Alamgir Road, Karachi. (ELI-00072) | Redax S.P.A Via Galilei 46025 PoggioRusco N. 18 Italy. FSC of Italy provided. | REDAX Thoracic Catheter (PVC). Claimed Shelf-life: 60-months. Class: B. Codes and sizes | PVC Straight Thoracic Catheter PVC Angeled Thoracic Catheter Trocar Thoracic Catheter. | Approved as the firm submitted the original (importer's copy) of fee |

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| | | | as per FSC. | | challan. |
| 80. | -do- | Primed HalberstadtMedizintechnik GmbH Str.des 20. Juli 1, 38820 Halberstadt. Germany. FSC of Germany provided. | PRIVAC (High Vaccum System). Claimed Shelf-life: 36-months. Class: B. Codes and sizes as per FSC. | High Vaccum System. (Redco) | Approved as the firm submitted the original (importer's copy) of fee challan. |
| 81. | -do- | Ultra for Medical Products Co. (ULTRAMED), 64 Nakhla El-Motaity St., Triumph Square, Hellipolis, Cairo, Egypt. FSC of Spain provided. | ULTRAFLOXON (Intravenous Cannula with injection Port), Claimed Shelf-life: 60-months. Class: B. Codes and sizes as per FSC. | Intravenous Cannula with injection Port. | Approved as the firm submitted the original (importer's copy) of fee challan. |

10. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

| S.# | Name of Firm (s) | Name of Manufacturer | Name of Medical Devices. | Brief Description | Decision |
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| 1. | M/s. Hashir Surgical Services, Office No.5, 2nd Floor, Syed's Tower, University Road, Peshawar. (ELI-00075) | Legal Manufacturer: M/s. Yafho Bio-Technology Co.,Ltd Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China. FSC China Valid till 20/12/2021 | Biopore Surgical Tape Fix Roll (Surgical Tape) Class A Shelf Life: 5 years. Code: 2.5cmx10m 5cmx10m 10cmx10m- 15cmx10m 20cmx10m | Fixing IV Cannula, Wound Dressing, Tracheal compress | Approved. Firm shall provide valid FQA before issuance of registration certificate. |
| 2. | -do- | Legal Manufacturer: M/s. Yafho Bio-Technology Co.,Ltd Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China. | Biopore Surgical PaperTape (Surgical tape) Class A Shelf Life: 5 years. | Biopore is a non-woven, lightweight, breathable surgical tape; uniformly coated with a hypoallergenic and sensitive under pressure | Approved. Firm shall provide valid FQA before issuance of registration certificate. |

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| | | FSC China Valid till 20/12/2021 | Code: 20mmx4.5m / box of 12 rolls, 20mmx4.5m / box of 10 rolls, 1.25cmx4.5m / box of 24 rolls, 2.5cmx4.5m / box of 12 rolls, 5cmx4.5m / box of 6 rolls, 7.5cmx4.5m / box of 4 rolls, 10cmx4.5m / box of 3 rolls, 2.5cmx10m / box of 12 rolls, 5cmx10m / box of 5 rolls, 7.5cmx10m / box of 4 rolls, 10cm, x10m / box of 3 rolls, | Acrylic adhesive on one side. Can be safely used as island dressing on hypersensitive parts of the body, e.g.: infant's skin, skin allergies, facial wounds. Secure fixation of devices; e.g.: tubes, catheters, measuring devices, etc. Suitable for repeated tape dressings. Backing type: Microporous non-woven fabric Backing weight: 30 g/m2 (± 3 g/m2) Adhesive type: Sensitive under pressure hypoallergenic Acrylic. Adhesive weight: 24 g/m2 (± 2 g/m2) | |
| 3. | -do- | Legal Manufacturer: M/s. Yafho Bio- Technology Co.,Ltd Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China. | Biopore Wound Dressing (Wound Dressing) Class A Shelf Life: 5 years. Code: | Used for wound care. | Approved. Firm shall provide valid FQA before issuance of registration certificate. |

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| | | FSC China Valid till 20/12/2021 | 5cmx8cm (2.2x4.5), 6cmx7cm (3x4)- 6cmx10cm (3x7), 9cmx10cm (5x6)- 9cmx15cm (5x10), 10cmx20cm (5x15)- 10cmx25cm 5x20), 10cmx30cm (5x25)-0cmx35cm (5x30), 10cmx40cm (5x35)- 8cmx8cm (Φ 5), 12cmx12cm (Φ 8)-.5cmx7.5cm (Φ 4.5), 12cmx14cm (8x9.5), | | |
| 4. | -do- | Legal Manufacturer: M/s. Yafho Bio- Technology Co.,Ltd Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China. FSC China FSC China Valid till 20/12/2021 | Biopore Surgical Drapes (Surgical Film/Draps) Class A Shelf Life: 5 years. Code: 45cmx45cm- 20cmx30cm, 28cmx45cm- 45cmx55cm, 28cmx30cm- 30cmx40cm, 32cmx45cm- 96cmx60cm, 10cmx14cm- 14cmx12cm, | It is used for protecting the wound site from Bacteria and dirt in an operation. | Approved. Firm shall provide valid FQA before issuance of registration certificate. |

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| | | | 15cmx28cm, | | |
| 5. | -do- | <p>Legal Manufacturer: M/s. Yafho Bio-Technology Co.,Ltd Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China.</p> <p>FSC China.</p> <p>FSC China Valid till 20/12/2021</p> | <p>Biopore IV Dressing</p> <p>Class A Shelf Life: 5 years.</p> <p>Code: 5cmx5.7cm-8.5cmx10.5cm</p> <p>3.8cmx4.5cm-7cmx8.5 8.5cmx11.5cm-6.5cmx7cm 7cmx9.5cm-5cmx5.7cm 4.4cmx6cm-4.4cmx4.4cm 6cmx7cm-10cmx12cm 7cmx9cm-9cmx10cm 9cmx15cm-9cmx20cm 9cmx25cm =cmx8cm (2x2)</p> | Fixing IV Cannula, Wound Dressing, Tracheal compress | <p>Approved.</p> <p>Firm shall provide valid FQA before issuance of registration certificate.</p> |
| 6. | -do- | <p>Legal Manufacturer: M/s. Yafho Bio-Technology Co.,Ltd</p> <p>Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China.</p> <p>FSC China Valid till 20/12/2021</p> | <p>Biopore Surgical Tape PE</p> <p>(Surgical tape)</p> <p>Class A Shelf Life: 5 years.</p> <p>Code: 20mmx4.5m / box of 12 rolls, 20mmx4.5m / box of 10 rolls, 1.25cmx4.5m / box of 24 rolls, 2.5cmx4.5m / box of 12 rolls, 5cmx4.5m / box of 6 rolls,</p> | Fixing IV Cannula, Wound Dressing, Tracheal compress | <p>Approved.</p> <p>Firm shall provide valid FQA before issuance of registration certificate.</p> |

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| | | | <p>7.5cmx4.5m / box of 4 rolls, 10cmx4.5m / box of 3 rolls, 2.5cmx10m / box of 12 rolls, 5cmx10m / box of 5 rolls, 7.5cmx10m / box of 4 rolls, 10cm,x10m / box of 3 rolls, 2.5cmx5m / box of 12 rolls, 5cmx5m / box of 6 rolls, 7.5cmx5m / box of 4 rolls, 10cmx5m / box of 3 rolls, 1.25cmx9.1m / box of 24 rolls 2.5cmx9.1m / box of 12 rolls, 5cmx9.1m / box of 6 rolls, 7.5cmx9.1m / box of 4 rolls, 10cmx9.1m / box of 3 rolls</p> | | |
| 7. | -do- | <p>Legal Manufacturer: M/s. Yafho Bio-Technology Co.,Ltd</p> <p>Second Floor Room 202 and Third Floor, No.81 Junfeng Road, Huangpu District Guangzhou 510760 Guangdong China.</p> <p>FSC China Valid till 20/12/2021</p> | <p>Biopore Zinc Oxide Tape (Zinc Oxide tape) Class A Shelf Life: 5 years. Code: 2.5cmx5m-cmx5m, 7.5cmx5m-10cmx5m 2.5cmx10m-5cmx10m, 7.5cmx10m-10cmx10m</p> | <p>Fixing IV Cannula, Wound Dressing, Tracheal compress, Heavy bandage dressing.</p> | <p>Approved. Firm shall provide valid FQA before issuance of registration certificate.</p> |

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| 8. | -do- | <p>Legal</p> <p>Manufacturer: RIASA S.R.L Bartolome Mitre 2990, Caseros, Buenos Aires, Argentina</p> <p>Factory: Pasteur 3424, Ciudadela, Buenos Aires, Argentina.</p> <p>FSC ARGENTINA Date of Issue 22/04/2019</p> | <p>HIPOALERGIC PORE</p> <p>(Microporous Hypoallergenic Surgical Tape)</p> <p>Code: 20mmx4.5m / boxof 12 rolls 20mmx4.5m / boxof 10 rolls 1.25cmx4.5m / boxof 24 rolls 2.5cmx4.5m / boxof 12 rolls 5cmx4.5m / boxof 6 rolls 7.5cmx4.5m / boxof 4 rolls 10cmx4.5m / boxof 3 rolls 2.5cmx10m / boxof 12 rolls 5cmx10m / boxof 5 rolls 7.5cmx10m / boxof 4 rolls 10cm,x10m / boxof 3 rolls 2.5cmx5m / boxof 12 rolls 5cmx5m / boxof 6 rolls 7.5cmx5m / boxof 4 rolls 10cmx5m / boxof 3 rolls 1.25cmx9.1m / boxof 24 rolls 2.5cmx9.1m / boxof 12 rolls 2.5cmx4.5m with plastic cover / boxof 12 rolls 5cmx4.5m with plastic cover / box of 6 rolls</p> | <p>Hipoalergic Pore is a non-woven, lightweight, breathable surgical tape; uniformly coated with a hypoallergenic and sensitive under pressure Hotmelt adhesive on one side. Can be safely used as island dressing on hypersensitive parts of the body, e.g.: infant's skin, skin allergies, facial wounds. Secure fixation of devices; e.g.: tubes, catheters, measuring devices, etc. Suitable for repeated tape dressings.</p> | Approved. |
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| | | | 1.25cmx9.1m with dispenser / box of 24 rolls 2.5cmx9.1m with dispenser / box of 12 rolls 5cmx9.1m with dispenser / box of 6 rolls 1.25cmx4.5m with dispenser / box of 24 rolls 2.5cmx4.5m with dispenser / box of 12 rolls 5cmx4.5m with dispenser / box of 6 rolls 1.25cmx9.1m with dispenser / box of 1 roll 2.5cmx9.1m with dispenser / box of 1 roll 5cmx9.1m with dispenser / box of 1 roll Class A Shelf Life: 5 years. | | |
| 9. | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) | Manufacturer: M/s Abbott Diagnostics Medical Co, Ltd. Chiba Plant 357, Matsudo-shi, Chiba-ken 270-2214, Japan | Determine™ Chase Buffer Code: 7D2243 Class A Shelf life: 24 months Fee submitted: Rs. 5,000/- | To be used with Determine™ products such as Syphilis, HIV 1/2, HBsAg, HIV Combo kit etc | Approved. |
| 10. | -do- | Manufacturer: M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany. | Alinity c Processing Module and ICT module (cluster) 1. Alinity c | Automated biochemical analyzer and the ICT module to be used on this | Approved. |

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| | | FSC Germany Issuance Date 24-02-2017 | Processing Module (analyzer) Code: 03R67-01 Shelf Life: N/A 2. ICT Module Code: 09D28-04 Shelf Life: N/A Class A Fee submitted: Rs. 5000/- | analyzer | |
|--|--|---|---|----------|--|

11. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Following applications for registration of Medical Devices for import were placed before the MDB in its different meetings and deferred for provision of documents. Now the firm has submitted documents

| S.# | Name of Firm (s)/Importer | Name of Manufacturer | Name of Medical Device | Brief Description | Decision |
|-----|--|---|---|--|------------------|
| 1. | M/s Intra Health, 56-A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00049) | Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich-Gauss-Strabe 7, 50259, Pulheim, Germany FSC Germany issued on 10-11-2016 | Descocid-N (Disinfectant) Class B Shelf Life: 03 Years Size: 1L, 5L, 10L Fee submitted: Rs.50,000/- | Surface disinfectant for medical devices Composition: 100 g contain: 13.2 g Benzalkonium chloride 6 g Didecyldimethyl ammonium chloride 4.5 g Formic acid | Approved. |
| 2. | -do- | Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich-Gauss-Strabe 7, 50259, Pulheim, Germany | Triacid-N (Disinfectant) Class C Shelf Life: 03 Years Size: 1L, 5L Fee submitted: | Aldehyde-free concentrate for the manual disinfection of medical instruments Composition: 100 g contain: 18 g N-Dodecylpropa | Approved. |

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|----|---|---|--|--|------------------|
| | | FSC Germany issued on 10-11-2016 | Rs.50,000/- | ne-1,3-diamine | |
| 3. | -do- | Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich-Gauss-Strabe 7, 50259, Pulheim, Germany FSC Germany issued on 10-11-2016 | Biguacid-S (Disinfectant) Class B Shelf Life: 05 Years Size: 1L, 5L, 10L Fee submitted: Rs.50,000/- | Aldehyde-free Surface disinfectant for medical devices Composition: 100 g contain: 17.5 g Didecyldimethyl ammonium chloride 4 g polyhexanide | Approved. |
| 4. | -do- | Manufacturer: M/s Antiseptica Dr. Hans-Joachim Molitor GmbH Carl-Friedrich-Gauss-Strabe 7, 50259, Pulheim, Germany FSC Germany issued on 10-11-2016 | AntisepticaCombi Instruments-N (Disinfectant) Class C Shelf Life: 03 Years Size: 1L, 5L Rs.50,000/- | For the manual disinfection of surgical instruments and laboratory equipment Composition: 100 g contain: 8 g Glutaraldehyde 5.75 g Formacetale | Approved. |
| 5. | M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) | Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 Manufacturing Site: Viant Medical Inc 620 Watson SW GR, MI USA 49504. FSC US FDA Valid till 01-04-2022 | DLP® Silicone Coronary Artery OstialCannulae Class D Code: 30315 30317 30320 Shelf Life: 3 Years Fee submitted: Rs. 50,000/- | Intended for use in conjunction with cardiopulmonary bypass surgery upto six hours or less for delivery of cardioplegia solutions directly to the coronary arteries. Sterile, single-use | Approved. |

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|----|------|--|--|--|------------------|
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| 6. | -do- | <p>Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432</p> <p>Manufacturing Site: Viant Medical Inc 620 Watson SW GR, MI USA 49504.</p> <p>FSC US FDA Valid till 01-04-2022</p> | <p>DLP® Pressure Catheter Placement Set Class D Shelf Life: 3 Years Codes: 50010 50011 50013 Fee submitted: Rs. 50,000/-</p> | <p>Intended for use in perioperative monitoring of left atrial pressure. Sterile, single-use</p> | Approved. |
| 7. | -do- | <p>Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432</p> <p>Manufacturing Site: Viant Medical Inc 620 Watson SW GR, MI USA 49504.</p> <p>FSC US FDA Valid till 01-04-2022</p> | <p>MiAR™ Cannulae (Aortic Root with Flow Guard) Class D Shelf Life: 3 Years Codes: 11012L Fee submitted: Rs. 50,000/-</p> | <p>Intended for use during cardiopulmonary bypass for delivery of cardioplegia for upto 6 hours, to aspirate air from the aorta after bypass and for use during cardiac surgery for median sternotomy or minimally invasive mini-sternotomy or right thoracotomy access using direct visualization technique Sterile, single-use</p> | Approved. |

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|-----|------|--|--|--|------------------|
| 8. | -do- | <p>Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432</p> <p>Manufacturing Site: Viant Medical Inc 620 Watson SW GR, MI USA 49504.</p> <p>FSC US FDA Valid till 01-04-2022</p> | <p>DLP® Single Stage Venous Cannulae (with Right Angled Tip) Class D Shelf Life: 3 Years Codes: 67312, 67314, 67316, 67318, 67320, 69312, 69314, 69316, 69318, 69320, 69322, 69324, 69328, 69331, 69424, 69428, 69431</p> <p>Fee submitted: Rs. 50,000/-</p> | <p>Intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery upto six hour or less. Sterile, single-use</p> | Approved. |
| 9. | -do- | <p>Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432</p> <p>Manufacturing Site: Viant Medical Inc 620 Watson SW GR, MI USA 49504. FSC US FDA Valid till 01-04-2022</p> | <p>DLP®ArteriomyCannulae (Coronary artery perfusion Catheter) Class D Shelf Life: 3 Years Codes: 31002, 31003, 31102, 31103, 31104, 31105, 31106 Fee submitted: Rs. 50,000/-</p> | <p>Intended for the perfusion of cardioplegia solution directly into a cardiac bypass graft or artery, or retrograde flushing of the free internal mammary artery with a vasodilator. Intended for use upto 6 hours or less. Sterile, single-use</p> | Approved. |
| 10. | -do- | <p>Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy.</p> | <p>Claria™ MRI CRT-D SureScan™ (Model: DTMA2D4-MR</p> | <p>A Sterile, implantable, battery-powered device</p> | Approved. |

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| | | <p>Minneapolis, MN USA</p> <p>Manufacturing Site: Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Toloxhenaz, Switzerland.</p> <p>(FSC Switzerland Valid till 06-03-2021)</p> | <p>Conditional)(Cardiac resynchronization therapy implantable defibrillator) Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-</p> | <p>consisting of the hermetically-sealed pacing pulse generator and an integrated defibrillation pulse generator with leads in the right ventricle, in a coronary vein over the left ventricle, and often in the right atrium (triple chamber).Single-use</p> | |
| 11. | <p>M/s Balta Impex, SH.40, Namco Centre, Cambell Street, Karachi. (ELI-00170)</p> | <p>Legal Manufacturer: Haiyan Kangyuan Medical Instrument Co., Ltd Songpodong Rd., Shengdang Town, Haiyan Zhejiang Province, China.</p> <p>(FSC China Valid till 08-07-2019)</p> <p>MHRA issuance 16-07-2020</p> | <p>Golden + Foley Catheter</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes: 6Fr, 8 Fr, 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28Fr</p> | <p>A Foley catheter is a thin, sterile tube inserted into the bladder to drain urine.</p> | Approved. |
| 12. | <p>M/s KM Enterprises, KM Mansion, 605-D Block MA Johor Town Lahore ELI: 00054.</p> | <p>Legal Manufacturer: M/s BiomaxRuber Industries SDN BHD. Malaysia +60360388699. FSC: Malaysia</p> | <p>BIOMAX (Latex Examination Gloves) Class-A Shelf Life: 05 years</p> | <p>• Provide technical details of mfg., QC, EPSP and labels (approved in country of origin) as per Form-</p> | Approved. |

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| | | Valid till: 21.10.2020 | | 7A. <ul style="list-style-type: none"> • Provide justifiable stability study data as per sr. no. 4(viii) of Form-7A. Provide the original and valid agency agreement & FSC of country of origin as per sr. no. 4(xiv-xv) of Form-7A. | |
| 13. | -do- | Legal Manufacturer M/s Changzhou Medical Appliance General Factory Co., Ltd China FSC: China Valid till: 06.06.2020 | AMD SURGICAL Disposable Face Mask. Class-A Shelf Life: | <ul style="list-style-type: none"> • Provide technical details of mfg., QC, EPSP and labels (approved in country of origin) as per Form-7A. • Provide justifiable stability study data as per sr. no. 4(viii) of Form-7A. Provide the original and valid agency agreement & FSC of country of origin as per sr. no. 4(xiv-xv) of Form-7A. | Approved. |

12. APPROVED SUBJECT TO CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Following applications for registration of Medical Devices for import were placed before the MDB in its different meetings and approved subject to provision of documents. Now firm has submitted documents:-

| S.# | Name of Firm (s)/Importer | Name of Manufacturer | Name of Medical Device | Brief Description | Decision |
|------------|---|--|---|---|--|
| 1. | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) | Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea. (FSC Korea Dated 11-08-2017) | SD BIOLINE Malaria Ag P.f/P.v Test Kit Class C (1)SD BIOLINE Malaria Ag P.f/P.v 05FK80 (25 Test/Kit) (2)SD BIOLINE Malaria Ag P.f/P.v 05FK83 (1 test/kit x 25 each) Shelf Life: 24 Months Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Malaria Testing | Approved as the product is WHO pre-qualified. The Board also approved the change of manufacturer name from M/s Standard Diagnostics Inc. to M/s Abbott Diagnostics Inc. 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099 Republic of Korea and brand name of the device from SD Bioline to BIOLINE Malaria Ag P.f/P.v Test Kit. |
| 2. | -do- | Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, | SD BIOLINE Malaria Ag P.f/Pan Test Kit Class C (1)SD BIOLINE Malaria Ag | In-Vitro Diagnostic Kit for Malaria Testing | Approved as the product is WHO pre-qualified. The Board also approved the change of manufacturer |

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| | | <p>Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.</p> <p>(FSC Korea Dated 11-08- 2017 WHO- PreQualified)</p> | <p>P.f/Pan 05FK60 (25 Test/Kit) (2)SD BIOLINE Malaria Ag P.f/Pan 05FK63 (1 test/kit x 25each) Shelf Life: 24 Months</p> <p>Fee Submitted: Rs.50,000/-</p> | | <p>name from M/s Standard Diagnostics Inc. to M/s Abbott Diagnostics Inc. 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099 Republic of Korea and brand name of the device from SD BIOLINE Malaria Ag P.f/Pan Test Kit to BIOLINE Malaria Ag P.f/Pan Test Kit.</p> |
| 3. | <p>M/s SY'AH Impex 1-6/15 Sector No. 5 Korangi Industrial Area Karachi- Pakistan ELI-00440</p> | <p>Legal Manufacturer: Shanghai Motex Healthcare Co., Ltd No. 369, JiasongZhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R. China. Valid FSC of China issued on 27th June 2020 valid till 27th June 2021</p> | <p>Shifa Surgical gloves Latex Powdered Surgical gloves</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Sizes: 6.0, 6.5, 7.0, 7.5. 8.0, 8.5)</p> | <p>Sterile disposable device intended to be worn on hands, usually in surgical setting, to provide barrier against potentially infectious material and other contaminants.</p> | <p>Approved the product on the basis of CE marked documents provided by the firm</p> |
| 4. | -do- | <p>Legal Manufacturer: Shanghai Motex Healthcare Co., Ltd No. 369, JiasongZhong Rd., Huaxin,</p> | <p>Shifa Examination Gloves Latex Examination Powdered gloves</p> | <p>Disposable device intended to be worn on hands or finger to prevent</p> | <p>Approved the product on the basis of CE marked documents provided by the firm</p> |

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| | | Qingpu, Shanghai 201708, P. R. China. Valid FSC of China issued on 27 th June 2020 valid till 27 th June 2021 | Class-A Shelf life: 5 years Sizes: S, M, L, XL | contamination between patient and examiner | |
| 5. | M/s Safi Brothers office S-22, Second floor Clock Tower, Shamsi Road, Mardan KPK. ELI-00337 | Legal Manufacturer Ningbo Yingmed Medical Instruments Co., Ltd Yingsheng Building, No, 456 Tai'an Road Southern Business Zone, 315199 Ningbo, China FSC: MHRA Date of issue 09.02.2018 | PROCARE I.V cannula with Wings and Heparin Cap Class: B Shelf life: 5 years Sizes: 14G-16G-18G- 20G-22G-24G) | I.V Cannula is used for insertion into body, for delivery or removal of fluid or gathering samples. | The Board approved the above mentioned medical device with brand name "PROCARE I.V cannula with Wings and Heparin Cap" |

13. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).

| S.# | Name of Firm (s)/Importer | Name of Manufacturer | Name of Medical Device | Brief Description | Decision |
|-----|--|--|--|--|--|
| 1. | M/s Moon Enterprises 5/6 Rabani Road, Old Anarkali, Lahore ELI-00356 | Manufacturer: M/s AGX Industries SDN BHD. No. 17 Lorong Sultan Mohamed 25 D/TAMAN Perindustrian Bandar Sultan Suleimann, 42000 PelabuhanKlang, Selangor, | Axglove Latex Examinations Gloves (powder free) Class A Shelf life: 3 years Fee submitted: 5,000/- | Powder free latex examination gloves, single- use, non- sterile | Deferred for provision of following documents:- Provide free sale certificate of Latex Examinations Gloves, powder free from Health Authority of Malaysia which shall be Original, Valid and Embassy |

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|--|--|--|--|--|--|
| | | <p>Malaysia</p> <p>FSC Malaysia not issued by Health Authority</p> | | | <p>attested.</p> <p>Shelf life not mentioned on form. Clearly state the shelf life of Axglove Latex Examinations Gloves, powder free and provide its stability studies</p> <p>Whether the product is available on free sale in reference countries provided in rule 67 of MDR, 2017? Provide original valid free sale certificate duly attested by Embassy of Pakistan.</p> <p>Letter of Authorization (LOA) provided from manufacturer abroad is copy and not notarized. Provide Letter of Authorization or agreement from manufacturer abroad which shall be original, notarized from the country of origin, signed & stamped, having issue date, validity, names and correct addresses of both manufacturer and importer and having name of medical devices for which Sole/Exclusive Authorization is given</p> <p>Details of manufacturing and</p> |
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| | | | | | <p>QC not provided. Provide the details of the manufacturing and quality control tests performed on the applied product specifically and not general quality plan and also provide certificate of analysis for the applied product</p> <p>ISO13485 copy provided which is not notarized. Provide notarized (original notarization) certificate</p> <p>Provide labels for latex gloves, powder free</p> <p>Submit separate application for other gloves</p> |
| 2. | <p>M/s Abdullah Traders, 3 Green Town, Ghous-ul-Azam Road, Multan</p> <p>ELI-00444</p> | <p>Manufacturer: M/s Nuclear Laser Medicine s.r.l. Viale Delle Industrie, 3 20090 Settala, Milan, Italy.</p> <p>FSC Italy not provided</p> | <p>SARS CoV-2 Real Time (Kit) Class C</p> <p>Codes: AA1571/96</p> <p>Shelf Life: 18 months</p> <p>Fee submitted: Rs. 50,000/-</p> | <p>For the determination of SARS-Cov-2 virus in nasopharyngeal and oropharyngeal swabs, sputum and bronchoalveolar lavages samples by real time RT-PCR technique. For professional use only</p> | <p>Deferred for provision of following documents:-</p> <ul style="list-style-type: none"> • Free sale certificate of the applied product which shall be Original, Valid and Embassy attested. • Letter of Authorization or agreement from manufacturer abroad which shall be original, notarized from the country of origin, signed & stamped, having |

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|----|--|--|---|--------------------|---|
| | | | | | <p>issue date, validity, names and correct addresses of both manufacturer and importer and having name of medical devices for which Sole/Exclusive Authorization is given.</p> <ul style="list-style-type: none"> • Original and Notarized copy of ISO13485. • Provide labels for AA1571/96 |
| 3. | Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi, 75300 Pakistan | <p>Legal manufacturer: Tan Sin Lian Industries SdnBhd No.1-12, Jalal Indah 2, Tamn Indah Jalan Haji Abdullah, 84000 Muar Johar Malaysia.</p> <p>FSC Malaysia issuance 02-12-2020</p> | <p>OPTISHIELD Examination Gloves (Powdered)</p> <p>Class-A</p> <p>Shelf life:</p> <p>Codes/ Sizes: X-small, Medium, Large, X-Large.</p> | Examination gloves | Approved. |

14. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

| Sr. No. | Name & Address of Establishment | Name of Medical Devices With Size | Brief Description | Decision |
|----------------|---|--|--------------------------|------------------|
| 1. | Usman Enterprises, Plot No. A116, Phase I, SITE, Super Highway, Karachi (ELM-0013) | <p>Nitripore Paper Surgical Tape</p> <p>Class A</p> <p>Shelf Life: 03 Years</p> <p>Rs.5000/-</p> <p>Tape dimension/ pack Size.</p> <p>Tape Dimension</p> <p>20mmx4.5 M(5 YDS) Box of Rolls</p> | Paper Surgical Tape | Approved. |

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| | | 20mmx9M(10 YDS) Box of 10 Rolls. | | |
| 2. | Paktex Industries, 2.5KM Tatlay Road, Sroyaabad, Kamoke. (ELM-0025) | Propore Adhesive Wound Bandages/Dressing 6cm x 7cm 9cm x 10cm 9cm x 15cm 9cm x 20cm 9cm x 25cm 9cm x 30cm Class A Shelf Life: 05 Years Rs. 5,000/- | Surgical wound bandages/dressing manufacturer specification | Approved. |
| 3. | -do- | Ziconoplast Adhesive Bandage 1 x 2.5M 2 x 2.5M 3 x 2.5M 4 x 2.5M 1 x 3.0M 2 x 3.0M 3 x 3.0M 4 x 3.0M Class A Shelf Life: 05 Years Rs. 5,000/- | Zinc Oxide Surgical Bandages/Strip/Tape BP 1988 | Approved. |

15. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)

| Sr. No. | Name & Address of Establishment | Name of Medical Devices With Size | Brief Description | Decision |
|----------------|---|---|-----------------------------------|------------------|
| 1. | Paktex Industries, 2.5 K.M. Tatlay Road, Sroyaabad, Kamoke Gujranwala (ELM-0025) | Gelo Foam Absorbable Gelatin Sponges USP29 1cm x 1cm x 1cm (1 x 4 Pcs) 2cm x 2cm x 2cm (1 x 10 Pcs) 2cm x 6cm x 0.7cm (12cm ²) (12-7), (1 x 12 Pcs) 8cm x 6.25cm x 1cm (50cm ²) (50) (1 x 4 Pcs) 8cm x 12.5cm x 1cm (100cm ²) (1 x 6Pcs) 8cm x 12.5cm x 0.2cm (100cm ²) (1 x 6 Pcs) | Absorbable Gelatin Sponges USP 29 | Approved. |

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| | | Class C Shelf Life: 05 Years Rs. 20,000/- | | |
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16. RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (FORM 7)

| Sr. No. | Name & Address of Establishment | Name of Medical Devices With Size | Decision |
|----------------|---|---|--|
| 1. | M/s Amson Vaccine & Pharma (Pvt) Ltd., 115 Industrial Triangle, Kahuta Road, Islamabad (ELM-0005) | Apple Butterfly Needle Set Class B Shelf Life: 05 Years Rs. 10,000/- Previous Reg No. 066578 | Deferred for verification of manufacturing facility of the product. |
| 2. | -do- | Apple IV Cannula Class B Shelf Life: 05 Years Rs.10,000/- Previous Reg No. 066576 | Deferred for verification of manufacturing facility of the product. |
| 3. | -do- | Apple Spinal/ LP Needle Class D Shelf Life: 05 Years Rs.10,000/- Previous Reg No. 066577 | Deferred for verification of manufacturing facility of the product. |
| 4. | -do- | Apple 1.0ml Syringe for Insulin Class B Shelf Life: 05 Years Rs.10,000/- PreviousReg No. 066575 | Approved subject to provision of copy of registration letter. |
| 5. | -do- | Apple Disposable Syringe 10ml, 20ml Class B | Approved subject to provision of copy of registration letter. |

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| | | Shelf Life: 05 Years Rs.10,000/- Previous Reg No. 069901 | |
| 6. | -do- | Apple Intravenous Infusion Set (IV Set) Class B Shelf Life: 05 Years Rs.10,000/- Previous Reg No. 066579 | Deferred for verification of manufacturing facility of the product and provision of copy of registration letter. |

17. RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

| Sr. No. | Name & Address of Establishment | Name of Medical Devices With Size | Brief Description | Decision |
|---------|--|--|-----------------------------|--|
| 1. | M/s Hafiz Pharma Industry, Neelam Cinema Road, Kamoke (ELM-0012) | Surgeon Plaster of Paris Bandage Plaster of Paris ...BPC 10cm x 2.7m 15cm x 2.7m Class A Shelf Life: 03 Years (Provide document evidence for claimed shelf life) Rs.5,000/- Previous Reg No. 044536 Sizes and Codes as already regd. | Plaster of Paris Bandage | Approved subject to provision of stability data for claimed shelf life. |
| 2. | -do- | Surgeon Cotton Bandage Cotton Bandage B.P Type II 12 of 5cm x 4m 12 of 10cm x 4m 12 of 15cm x 4m Class A Shelf Life: 03 Years (Provide document evidence for claimed shelf life) | Cotton Bandage B.P Type II. | Approved subject to provision of stability data for claimed shelf life |

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| | | Rs.5,000/- Previous Reg No. 044531 Sizes and Codes as already regd. | | |
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18. REGISTRATION OF MEDICAL DEVICES FOR EXPORT.

M/s Renacon Pharma Limited, Lahore has submitted below mentioned application for grant of registration of medical device for export to Srilanka under Medical Devices Rules, 2017:-

Decision: The Board discussed and decided as mentioned against each.

| Name & Address of Establishment | Name of Medical Devices With Size | Brief Description | Decision |
|--|---|--|------------------|
| M/s Renacon Pharma Limited, 18-KM, Ferozepur Road, OppNishtar Colony, Lahore. (ELM-0024) | Renacarb (ERBR) Hemodialysis Concentrate Composition: Part-A Sodium (Na ⁺) (mEq/L).....80-110 Potassium (K ⁺) (mEq/L).....0-3.0 Calcium (Ca ⁺⁺)(mEq/L).....0-4.0 Magnesium (Mg ⁺⁺)(mEq/L).....0-2.4 Chloride (Cl ⁺)(mEq/L).....90-120 Acetic Acid (CH ₃ COOH) (mEq/L)..2.5-10 Glucose (Dextrose) (mmol/L)0-12 Part-B Bicarbonate (HCO ₃) (mEq/L).....Not more than 45 Class C Shelf Life: 3 years Rs. 20,000/- | Use for all the patients who need hemodialysis e.g. End-stage- kidney failure and Autre renal failure with Uremia. | Approved. |

Case is being presented before MDB for consideration please.

19. APPLICATIONS FOR PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.

M/s DRK Pharma Solution (Pvt) Limited, 1st Floor, Building No.2, The Enterprise 15 KM Multan Road, Lahore have stated that they are Licensed Clinical Research Organization having License No.CRO-0001 dated 11th October, 2019 and got approval of clinical trial from Pharmacy

Services Division of DRAP titled "*Phase III Randomized, Double-blind, Placebo-controlled Clinical Trial in 18 Years of Age and Above to Determine the Safety and Efficacy of ZF2001, a Recombinant Novel Coronavirus Vaccine (CHO cell) for Prevention of COVID-19*". It is a Phase-III multi-country, multi-center clinical trial, currently ongoing in 5 countries i.e. **China, Pakistan, Indonesia, Equador, Uzbekistan.**

They have stated that to standardize the results of screening tests (Covid-19 IgG/IgM antibody test and RT-PCR test), the sponsor of this clinical trial has used the following same kits in all the participating countries. Therefore, they have requested to give approval for the import of the following testing kits from China for screening of the subjects to be enrolled in the trial:-

| S.# | Name of Medical Device | Name of Manufacture | No. of Cartons | No. of Units per Carton | Quantity (Unit) | Qty.App. for Clinical Trial |
|-----|--|--|----------------|-------------------------|-----------------|-----------------------------|
| 1. | Nucleic Acid Extraction from SARS-CoV-2. | Shanghai Fosun Long March Medical Sciences Co. Ltd, China. | 250 | 98 | 24,500 | 18,000 |
| 2. | SARS-CoV-2 nucleic acid detection kit (RT-PCR) | Shanghai Fosun Long March Medical Sciences Co. Ltd, China. | 250 | 98 | 24,500 | 18,000 |
| 3. | SARS-CoV-2 IgM/IgG Antibody detection kit. | M/s Nanjing Vazyme Medical Technology, Co, Ltd, China. | 400 | 50 | 20,000 | 20,000 |
| 4. | Specimen Collection Swab | M/s Jiangsu Jianyou Medical Technology Co., Ltd, China. | 120 | 200 | 24,000 | 24,000 |
| 5. | Universal Transport Medium (UTM) | Shanghai Fosun Long March Medical Sciences Co. Ltd, China. | 240 | 100 | 24,000 | 24,000 |

Decision: The MDB discussed the matter at length and decided to approve the issuance of Form 10 for above mentioned medical devices to be used in the clinical trial titled "*Phase III Randomized, Double-blind, Placebo-controlled Clinical Trial in*

18 Years of Age and Above to Determine the Safety and Efficacy of ZF2001, a Recombinant Novel Coronavirus Vaccine (CHO cell) for Prevention of COVID-19" at Aga Khan University Hospital, Karachi, University of Health Sciences, Lahore and National Hospital and Medical Centre, Lahore.

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