

**DECISIONS OF THE 20<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)  
HELD ON 21-09-2020**

**1. REGISTRATION OF UMBILIZER FOR M/S FEROZSONS (PVT) LTD.**

**Decision:-** The Board discussed the matter at length and decided to ask the firm to provide Free Sale Certificate of the product from the country of origin. Furthermore, the firm may be facilitated by DRAP if the product is intended to be manufactured locally.

**2. (NECOP) FOR ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES AND PRODUCT REGISTRATION - COVRAID ARTIFICIAL INTELLIGENCE-BASED XRAY SOFTWARE TOOL FOR DETECTION OF COVID-19.**

**Decision:-**Dr. Muhammad Nadeem, member of MDB as well as Chairman of Expert Group for the assessment /evaluation/testing of locally manufactured software as Diagnostic tools explained the matter to MDB and MDB decided as under:-

- i) **Clinical demonstration of the Software by NECOP before Dr. Muhammad Nadeem, an MIS professional and clinical radiologists of two hospitals namely Prof. Dr. Kiran Farooq, Fauji Foundation Hospital, Rawalpindi and Dr. Atif Rana, Shifa International Hospital, Islamabad. The Software demo shall include X-rays of normal, Covid positive, Covid positive with lungs involvement and Covid positive without lungs involvement.**
- ii) **Feedback should be sought from the department heads/radiologist where the system is already deployed. Following are the questions on the feedback form/template**
  - a. **Is this solution is used and deployed in the routine clinical work?**
  - b. **Is this solution user friendly and intuitive?**
  - c. **How do you find its clinical utility and accuracy?**
  - d. **What are the best features/strength of the solution?**
  - e. **What is the weaknesses/areas of improvement of the solution?**
  - f. **Can the system be used for diagnosis of Covid without radiologist?**
  - g. **How do you find the solution for the diagnosis of diseases, other than Covid?**
  - h. **Do you think the system is safe in clinical practice?**
  - i. **Would you recommend it to other radiology departments,**
- iii) **Software be sent to Center of excellence for Artificial intelligence, University of the Punjab for validation.**
- iv) **Followup meetings of expert group with NECOP officials shall be carried out to address the queries / questions of expert group.**
- v) **Board recommended the testing of software on atleast 1000 cases having mix of screening, Covid and non-Covid respiratory pathology cases in various hospitls.**

**3. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.**

S.No	Name of Establishment	Director/Proprietor/partners	Name of panel Inspector (s)	Decision
1.	M/s Premium Global Health  House No. 1-A, St. No. 32, Main Service Road, 9 <sup>th</sup> Avenue, F-8/1, Islamabad.  <b>Godown:</b> 2 <sup>nd</sup> Floor, Mumtaz Plaza, No. 31, tipu Boulevard, South Sector D, Phase 2, D.H.A., Islamabad	Mr. Navid Ahsan  Mr. Fahad Hashmi	Mr. SardarShabbir, Drug Inspector, ICT, Islamabad  Mrs. Unum Zia Shamsi, AD-IV (MDMC), DRAP, Islamabad	<b>Deferred</b> till the inspection of the premises by the panel

**4. REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s Vertex Medical (Pvt) Ltd., 70-B-1, Gulberg III, Lahore (ELI-00150)	<b>Legal Manufacture:</b> M/s Dragerwerk AG & Co. KGaAMoislingerAl lee 53-55 23542 Lubeck, Germany.  FSC Germany Issuance Date 15-10-2019	Drager Reusable Silicon Anaesthesia Mask  Class B  Shelf Life: Not Mention  Rs. 25,000/-  Mask Silicon Inf Small 0 reus Mask Silicon Inf large 1 reus Mask Silicon Child sm 2 reus Mask Silicon Child lg 3 reus Mask Silicon Adult sm 4 reus Mask Silicon Adult lg 5 reus Mask Silicon PremieXS 00 reus	Reusable Silicon Anaesthesia Mask	<b>Approved</b> subject to provision of following documents:- 1. All Original documents to be provided duly attested 2. Stability Studies Required 3. Manufacturing & QC Process details Required 4. Essential Principle of Safety & Performance Required 5. Original DOC Required
2.	-do-	<b>Legal Manufacture:</b> M/s Dragerwerk AG & Co. KGaAMoislingerAl	Drager Breathing Bags  Class B	Breathing Bags	<b>Approved</b> subject to provision of following documents:-

		lee 53-55 23542 Lubeck, Germany.  FSC Germany Issuance Date (15-10-2019)	Shelf Life: Not Mention  Rs. 25,000/-  VentStar Bag Set (N) 110 VentStar Breathing Bag 0.5L VentStar Breathing Bag 1L VentStar Breathing Bag 2L VentStar Breathing Bag 3L		1. All Original documents to be provided duly attested 2. Stability Studies Required 3. Manufacturing & QC Process Details Required 4. Essential Principle of Safety & Performance Required 5. Original DOC Required
3.	-do-	<b>Legal Manufacture:</b> M/s Dragerwerk AG & Co. KGaAMoislingerAl lee 53-55 23542 Lubeck, Germany.  FSC Germany Issuance Date 15-10-2019	Drager Disposable Anaesthesia Masks  Class B  Shelf Life: Not Mention  Rs. 25,000/-  Mask LiteStar 1 w/o hook Mask LiteStar 2 w/o hook Mask LiteStar 3 w/o hook Mask LiteStar 4 w/o hook Mask LiteStar 5 w/o hook Mask LiteStar 6 w/o hook	Disposable Anaesthesia Masks	<b>Approved</b> subject to provision of following documents:- 1. All Original documents to be provided duly attested 2. Stability Studies Required 3. Manufacturing & QC Process Details Required 4. Essential Principle of Safety & Performance Required 5. Original DOC Required
4.	M/s Hashir Surgical Services  1. Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar.  2. Office No.05, 2nd Floor,	<b>Legal Manufacture:</b> M/s LR No.5025/1239 Msumarini- Mombasa-Malindi Rd P.O BOX 80713- 80100 Mombasa- Kenya	REVITAL CADY Auto Disable Syringes for immunization  0.05ml, 0.1ml, 0.5ml, 2ml, 5ml, 10ml  Class B  Shelf Life: 12 months	Auto Disable Syringes for immunization	<b>Approved</b> subject to provision of following documents:- 1. All Original documents to be provided duly attested as provided documents are copies without

	Syed's Tower, University Road, Peshawar. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar	FSC Kenya valid till (31-12-2019)	Rs.25,000/-		attestation and notarization 2. Reference Country Free Sale Certificate Required 3. Provide QMS Certificate duly notarized 4. Provide FQA Certificate duly notarized 5. Provide labels of all applied sizes.
5.	M/s Grace Pharmaceuticals, Office No. 503, 5th Floor, Plot No.42C/2, Lane No.8, Bukhari Commercial, DHA Phase-6, Karachi  (ELI-00254)	<b>Legal Manufacturer:</b> M/s Jiangxi Hongda Medical Equipment Group Ltd., No. 39, South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China  (FSC China Valid 26-11-2020)	Alpha Auto-Disable Syringe for fixed dose (with Needle)  Class B  Shelf Life: 4 Years  0.5ml, 1ml, 2ml,5ml	Sterile auto- disable syringe for fixed dose is used for delivering a fixed dose of vaccine.	<b>ALREADY APPROVED IN 16<sup>TH</sup> MDB</b> All Original documents to be provided duly attested  Reference Country Free Sale Certificate (FSC) Required  Essential Principle of Safety & Performance Required  Provide labels of all applied sizes
6.	M/s DKT Pakistan (Pvt) Ltd RJ Building 4th Floor, Plot No. 37-C, Stadium Lane No. 2 Stadium Commercial Area Phase V DHA Karachi (ELI-00515)	<b>Legal Manufacturer:</b> INJEFLEX Industria E Comercio De, Dispositivos, Produtos Medicos LTDA RuaCiprianoBarata 575 -Vila Monumento Sao Paulo - SP 04205- 000 Brazil  FSC Brazil (01-01-2027)	Pro-Green Tcu 380  1. Slim Line Tcu 380S 2. UltraloadTcu 380S with Steriload applicator. 3. Classic Tcu 380A.  Class D  Group Family  Claimed Shelf Life: 7 Years	Intra Uterine Device.	Provided documents are of <b>OPTIMA</b> whereas firm has applied in the name of <b>Pro- Green</b> , while on Free Sale Certificate of Brazil the name of product is female contraceptive devices  Free Sale Certificate (FSC)

			Rs. 50,000/- No codes and sizes on FSC		of Brazil provided with the validity of Jan-2002 to Jan-2027 (No RRA certificate as per Rule 67 provided)  Provided GMP Certificate is Expired on April 2020.  The shelf life, manufacturing & QC details and Technical Documents yet to be evaluated
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**5. REGISTRATION OF MEDICAL DEVICES FOR EXPORT (FORM 7).**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description
1	Uniferoz (Pvt) Ltd, 32/8 & 33/2, Sector 15, Korangi Industrial Area, Karachi (ELM-0011)	Prostat First Aid Woven Adhesive Bandage (Fabric Base)  Class B  Shelf Life: Not Mentioned  Rs. 20,000/-  Codes as Sizes as mentioned in the form	Adhesive Bandages (Sterile)
2	Uniferoz (Pvt) Ltd, 32/8 & 33/2, Sector 15, Korangi Industrial Area, Karachi (ELM-0011)	Prostat First Aid Plastic Adhesive Bandage (PE Base)  Class B  Shelf Life: Not Mentioned	Adhesive Bandages (Sterile)

		Rs. 20,000/-  Codes as Sizes as mentioned in the form	
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**Decision: The Board approved the registration of above products for export. In order to facilitate export, the Board delegated the power of issuing export registration to Secretary MDB with the approval of Chairman, MDB and the cases shall be presented to MDB for ratification.**

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