DECISIONS OF THE 18TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 29-07-2020

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 Bio-Biz (Pvt) Ltd, **Head Office** No. 104-7, Al Hafeez Business Center, 89 B-3, Gulberg III, Lahore. **Godown**: Plot No. 12, Phase I-A, M-3 Industrial City, Sahianwala, Faisalabad.	Muhammad Bhatti Muhammad Imran Masood	No	**Approved** for storage of non-cold chain medical devices subject to provision of DSL.

2. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.

S. No	Name of Establishment & Directors	Address	Name of Production Incharge	Name of QC Incharge		
1.	**M/s The National Radio Telecommuni-**	T&T Complex, Haripur,	Mr.Ayaz Sarwer (BS Electrical	Lt Col Usman (R) (BSc		

	cations Corporation (Pvt) Ltd., & Brig. Tofique Ahmed (Managing Director) CNIC: 34202-3874002-1	KPK	Engineering) CNIC: 13302-5957627-9	Electronics & Telecomm Engineering), CNIC: 42301-7626465-5		
Decision: **Dr. Muhammad Shafique, being member of the inspection team briefed the Board regarding shortcomings of the facility. He was of the view that M/S NRTC was deficient in documentation required as per ISO 13485 and there was no proper process flow. THe Board cognizant of the fact that there was no dedicated QC Laboratory, technical person not hired with required qualification and segration required for raw materialsw and finished goods agreed with the recommendations of the panel of experts to revisit the facility for verification of compliance to non-conformities pointed out by the panel. Regarding the matter of utilizing shared facility, the Board decided that the same facility with clear segregated area for ventilators may be used till the time a dedicated facility is built. The Board also asked for technical assessment evaluation report of the ventilator from Pakistan Engineering Council.**						
2.	**M/s Alsons Industies (Pvt.) Ltd., Karachi** & Mr Akber Allana, Director Mr M. A Basit Qureshi, Director (Power and Energy) Mr Nadeem Mahmood, G.M QA/QC	S/18 S.I.T.E., Karachi, 75730	Mr Safdar Hussain Qureshi (Bio Medical Engineer)	Mr Naveed Qadir (Bio-Medical Engineer)		

Decision:	**The Board after through discussion advised M/s Alsons Industries (Pvt) Ltd to comply with the critical observations / non-conformities pointed out by the panel and decided to resend panel of experts for verification of the same.**					
3.	**M/s BIO-Biz (Pvt) Ltd., Faisalabad.** & Muhammad Imran, MD	Plot No. 12, Phase-1A, M3 Industrial City, Sahianwala, Faisalabad	Mr. Abdul Raza, Pharm-D	Mr. Zia Urrehman		
Decision:	**The Board after discussion decided to defer the grant of Establishment License to Manufacture Medical Devices since the firm does not have in-house QC testing facility.**					

3. <u>REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE.</u>

Sr. No	Name and Addresses of Establishment	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	
1.	M/s Alsons Industries (Pvt.) Ltd, S/18 S.I.T.E., Karachi	ALNNO-VENTURA CPAP Device Class C Shelf Life: 5 Years (claimed by the manufacturer) Fee of Rs.20,000/-	Continuous positive airway pressure (CPAP)/High-flow nasal oxygen therapy (HFNO) device for patients with breathing difficulties.	

Discussion & Decision:

The Board was informed that the device is an open source Mercedes AMV-HPP and UCL design. The expert members of the Board were of considerate opinion that:

The device is a good step towards local manufacturing which is appreciated. However, at the same time, it is critical life-saving equipment and necessary safeguard measures needs to be ensured to protect the life of critically sick patients. Hence, **decided** that following steps must be taken in **shortest possible time** before grant of approval of emergency use authorization of said device:

i. Design validation report by PEC of the device is required.
ii. Considering the delicate nature of the device, being life-saving and used in critical care

management, Board decided to get it clinically evaluated / assessed from at least two public sector hospitals either through Pharmacy Services Division, DRAP or otherwise.

4. CONSTRAINTS AND STATUTORY HINDRANCE / OVERLAPPING OF LEGAL PROVISIONS REGARDING THERAPEUTIC GOODS' ADVERTISEMENT.

Decision:

The Board was apprised at length regarding the working and procedure of notified Advertisement Committee functional under Pharmacy Services Division and that they have expertise to decide on advertisement matters. The Board decided to delegate its power of regulating advertisements to the Committee on Advertisement {SRO 983(I)/2013}. The Board has also desired that one member of Medical Device Division may also be included in Advisory Committee for cases related to medical devices.

5. STANDARDIZATION OF PERSONAL PROTECTIVE EQUIPMENTS (PPEs)

Relief Commissioner, Provincial Disaster Management Authority, Punjab has informed that in the wake of relentless spread of COVID-19, the demand for Personal Protection Equipment (PPE) has increased manifolds but supplies are not catching up. The situation is further aggravated due to non-availability of approved and standardized specifications for PPE. Consequently, provision of healthcare services to affected population is not optimal.

They further informed that in order to plug this gap, Government of Punjab constituted a committee of experts to propose recommendations for standardization of PPE and requisite level of its usage. After detailed deliberation by the aforesaid committee, recommendations for standardization of PPE have been formulated. These were presented before the Cabinet Committee on Corona Control of Government of the Punjab and are being forwarded to Drug Regulatory Authority of Pakistan for consideration and approval. This is in pursuance of directions of National Command and Operation Center, Islamabad.

The recommendations regarding standardization of PPEs were presented in 81st meeting of the Drug Regulatory Authority of Pakistan held on 05-05-2020 and the Authority decided as follow;

The Authority decided to adopt either of the following:-

I. ***WHO PPEs recommendations as described in "Disease Commodity Package for Noval Coronavirus" as provided under section 7(c)(ix) and 7(t) of DRAP Act, 2012***

OR

II. ***Standards approved for PPEs by Reference Regulatory Authorities defined under Rule 67(1)(a) of Medical Devices Rules, 2017.***
And referred the recommendations of the Standardization Committee constituted by the Provincial Government of Punjab to the Medical Devices Board for detailed deliberation.

Accordingly the said decision of the Authority was communicated to Relief Commissioner, PDMA-Punjab.

The key points discussed in the meeting of the Standardization Committee whose minutes have been forwarded to DRAP are as follows:

1. Constituents of PPE.
2. Requisite chemical and physical properties of PPE.
3. Requisite standards conforming to the aforementioned properties.
4. Deliberation upon specifications of PPE adopted by Health Department.
5. Proposed testing methods of PPE as per international best standards.
6. Availability of testing facilities for these testing methods in Punjab/Pakistan.
7. Requisite/rational standards and protocol for usage PPE.
8. Best possible way forward in selection of PPE during the emergency.

With reference to the aforesaid minutes, following is submitted:

a) That the descriptions of PPEs, technical specifications, standards defined for testing and other stated information is as per WHO recommendations in "*Disease Commodity Package for Noval Coronavirus"* published on 11-01-2020 for Novel Coronavirus.

b) The committee discussed the ground realities regarding testing facilities available in Punjab and identified few tests that can be performed in various lab/institutions of Punjab and for other tests neither the facility nor the standards are available.

c) They concluded that for PPEs like N95/KN95, latex gloves and goggles, only imported products as per WHO recommendations shall be procured. Similarly, for

PPEs like gloves (non-sterile), surgical masks, shoe covers and face shield that are locally manufactured, the committee identified certain tests to be performed by local manufacturer subject to the availability of requisite labs/equipment.

Disease Commodity Packages (DCPs) have been designed by World Health Organization (WHO) involving an organization-wide, "team-of-experts" and consultation with key external partners. These DCPs are a series of disease specific datasheets that list the critical commodities and the technical specifications for each commodity per disease. In the wake of COVID-19 emergency, WHO has published two DCPs namely ***Disease Commodity Package for Novel Coronavirus*** dated 11-1-2020 and 06-03-2020.

The following tabulated form is a comparative overview of WHO published DCP and the recommendations of PMDA-Punjab.

Gown			
Type/Variant of PPE	**WHO Recommended std. (Disease commodity package dated 06-03-2020)**	**PDMA, Punjab (Produced as in Receipt)**	**Comment**
Single-use, length mid-calf.	i. EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC; ii. FDA Class I or II medical device, or equivalent; iii. EN-13795 any performance level; iv. AAMI PB70 all levels acceptable, or equivalent.	• The Committee endorsed the Recommendations of Sub-Committee and decided following specifications. • Materials: Non-Woven Polypropylene Laminated with Porous PE Layer (Preferably 15-20 Micrometer) OR • Spunbound-Meltblown-Spunbound (SMS, Min 3 Layers) preferably coated with fluoropolymer. • GSM > 50 with	• PDMA recommends ASTM F2407-06 standard which is much stringent while WHO recommends EN 13795 or FDA Class I or II medical device • PDMA recommends that most of the testing facilities are not available in Pakistan. • The design of gown recommended by PMDA is different from that recommended

		comfort of use. • The Gown must be seamless with A–Plus quality of Zipper etc. • Sterilization must be ensured through a). Radiation (Gamma) method. b). Chemical Method (Ethylene oxide). Since most of the tests are not available in Pakistan and due to emergency situation the locally available test must be conducted.	by WHO w.r.t hood, zip in front, and tape on seems, thick material and restricted only to large size. • The PDMA put restriction on material of gowns. However, PDMA doesn't describe specifications (materials and build of gowns) for compliance in accordance with any international standard.
Particulate respirator, grade N95 or higher			
N95 or FFP2 respirator, or higher Good breathability with design that does not collapse against the mouth (e.g. duckbill, cup shaped)	i. Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040, and CDC NIOSH, or ii. Minimum "FFP2 according to EN 149, EU PPE iii. Regulation 2016/42 Category III, or equivalent	The committee decided that:- Only imported N-95(KN-95 is Chinese version) Mask can be procured as per WHO Standards. Following N95 mask can be used as per requirement: - •N95 with / without respirator according to US NIOSH or •'FFP2' according to EN 149 or •KN 95 according to China GB-2626-2006 (Not Appropriate for level 1) Any of the aforementioned International Certification for	• <u>There is no difference between WHO and PDMA, recommendations.</u> • However, the PDMA, Punjab specified name of a Chinese brand i.e. KN-95 in their recommendations. • PMDA recommended only imported particulate respirators for their procurement, whereas a number of local manufacturers of particulate

		offered batch is mandatory.	respirators are approaching to DRAP for registration. • PDMA recommended 5 tests required in accordance with EN 149 and at the same time mentioned that no testing facility is available in Pakistan.
Surgical Mask			
<u>Mask, surgical - healthcare worker</u> Surgical mask, good breathability, internal and external faces should be clearly identified Type II or higher	• EU MDD Directive 93/42/EEC Category III or equivalent • EN 14683 Type II, IR, IIR • ASTM F2100 minimum level 1 or equivalent	The committee decided that:- In case of Imported Masks, provision of requisite International certifications for offered lot / batch will be mandatory as per applicable Annex-C. For Locally Manufactured Masks: A three layer structure (Two outer filtering layers and middle absorbing layer of extra fine glass fiber or synthetic microfibers i-e PP, Polystyrene etc.) ranging from 10-100 GSM with or without nose holder along with elastic ear holders with reasonable length and comfort of use.	The PDMA, Punjab taken same standards from WHO DCP version 1 on COVID-19 However currently version 4 of COVID-19 is prevailing. Furthermore, the recommendations of PDMA, Punjab for locally manufactured masks are incomplete and doesn't describe specifications for compliance in accordance with any international standard. PDMA recommended 5 tests in accordance with ASTM 2100-19 and at the same time mentioned experimental rig is required.
Mask, surgical - patient **Surgical mask,** good breathability,	• EN 14683 any type including Type I • ASTM F2100 minimum level 1		

internal and external faces should be clearly identified Type I	or equivalent		
Gloves			
Gloves, examination, non-sterile Gloves, examination, nitrile, powder-free, non-sterile, single-use Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Sizes: small, medium, large.	• EU MDD Directive 93/42/EEC Category III • EU PPE Regulation 2016/425 Category III • EN 455 • **EN 374*** • ANSI/ISEA 105, **• ASTM D6319,** or equivalent set of standards	The committee decided that:- Only Imported Latex Gloves can be procured as per WHO Standards as proposed by sub-committee Annex-C Provision of requisite International Certification for offered batch / lot is mandatory. In case of Local manufacturing of Non Sterile Gloves all test including freedom from holes, physical dimensions test and physical requirement test which are available in Pakistan must be conducted.	The sub committee of PDMA proposed that WHO specifications can be adopted for procurement. **The WHO recommends nitrile gloves however the PDMA is recommending latex gloves as per WHO standards which is contradictory.** The WHO provides category wise recommendations for gloves however the PDMA recommendations intermixes the two different Gloves (Sterile and Non-sterile).
Gloves, examination or surgical, sterile Gloves - surgical or examination - nitrile, powder-free, sterile, single-use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Sizes: small, medium, large.	• EU MDD Directive 93/42/EEC Category III, • EU PPE Regulation 2016/425 Category III, • EN 455, • ANSI/ISEA 105, **• ASTM D6319** or equivalent		
Goggles			
Good seal with the skin of the face, flexible PVC frame to easily fit with all face contours with even pressure, enclose eyes and the surrounding areas, accommodate wearers with prescription glasses, clear plastic lens with fog and	• EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1 or equivalent	The committee decided that: - Only Imported Goggles can be procured as per WHO Standard. Provision of requisite International certifications for offered lot / batch will be mandatory as per applicable Annex-C.	The sub committee of PDMA proposed that WHO specifications can be adopted for procurement.

scratch resistant treatments, adjustable band to secure firmly so as not to become loose during clinical activity, indirect venting to avoid fogging. May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.			
Face Shield			
Made of clear plastic and providing good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog resistant (preferable). Completely cover the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	• EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1 or equivalent	The committee decided that: - Imported Face Shield can be used as per WHO Standard. Provision of requisite International certifications for offered lot / batch will be mandatory as per applicable Annex-C. In Case of Local Manufacturing, Materials: PC PETG PET Thickness: 20-40 micrometer Material Identification, Material Mechanical testing and physical dimensions are mandatory.	The sub committee of PDMA proposed that WHO specifications can be adopted for procurement. Furthermore, the recommendations of PDMA, Punjab for locally manufactured face shield are incomplete and doesn't describe specifications for compliance in accordance with any international standard.
Sanitizer (Alcohol-based hand rub)			
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	Formulation: Concentrated alcohol 70-75% Glycerol 1% Polyethylene glycol 0.01%	Provision of requisite International certifications for offered lot / batch will be mandatory as per applicable Annex-C. In Case of Local Manufacturing, Bacterial Resistance Test according to ASTM E2755 or Equivalent ISO/EN Standard test will be mandatory.	a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured; OR Isopropyl Alcohol (75%, v/v) in an aqueous solution. b. Glycerol (1.45% v/v). c. Hydrogen peroxide (0.125% v/v). **However, the PDMA recommended composition of hand sanitizer is different from the one recommended by WHO.**
Shoe Cover			
----	No recommendations given by WHO vide their DCP on COVID-19 v4	The committee decided that: - Provision of requisite International certifications for offered lot / batch will be mandatory as per applicable Annex-C. In Case of Local Manufacturing of shoe covers, Impact and Hydrostatic Penetration tests and strength tests are mandatory.	No recommendations given by WHO vide their DCP on COVID-19 v4 However, the PDMA recommends the same standard as that of gown i.e. ASTM 2407 titled Standard specification for surgical gown intended for use in healthcare facilities. As per online sources the shoe cover is a medical device vide Global Medical Device Nomenclature number 13574, however, standards could not be found.

Long Shoes			
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Furthermore, it is submitted that an updated version of the WHO's ***Disease Commodity Package for Novel Coronavirus (COVID-19 v5)*** dated 21st July, 2020 has been published recently (Placed at Annexure-A)

Decision: The Board deliberated the matter at length and decided to endorse/approve the standards recommended by WHO *Disease Commodity Package (DCP) for Novel Coronavirus (COVID-19 v4)* dated 06-03-2020 and *Disease Commodity Package for Novel Coronavirus (COVID-19 v5)* dated 21-07-2020 and decided on standards of PPE as mentioned against each in the last column i.e 5:-

Description of PPE as per WHO DCP dated 21-07-2020.	Standards proposed by PDMA, Punjab	WHO Recommended std. (DCP dated 06-03-2020) ADOPTED BY AUTHORITY	WHO Recommended std. (DCP dated 21-07-2020) LATEST	Decision
(1)	(2)	(3)	(4)	(5)
Gown				
Gown, surgical Single use, disposable, nonwoven material, length mid-calf, sterile or non-sterile. Critical zones may be more fluid resistant than non-critical zones. Or Single use, woven material, length mid-calf, sterilizable. Critical zones may be more fluid resistant than noncritical zones.	ASTM F2407-06	• EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC; • FDA Class I or II medical device, or equivalent; • EN-13795 any performance level; • AAMI PB70 all levels acceptable, or equivalent.	• AAMI PB70 • ASTM F2407 • EN 13795 • EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O • YY/T 0506, or alternative equivalent set of standards • EN 556, if sterile, or alternative equivalent set of standards.	• EN-13795 any performance level; • AAMI PB70 all levels acceptable, or equivalent • ASTM F2407 • EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O • YY/T 0506, or alternative equivalent set of standards • EN 556, if sterile, or alternative equivalent set of standards.
Gown, isolation Single use, disposable, made of nonwoven material, length mid-calf. Sizes S, M, L May also be reusable, woven, length mid-calf, sizes S, M, L. Critical zones may be more fluid resistant than non-critical zones			• AAMI PB70 (Level 1-3) • ASTM F3352 • EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O • AAMI PB70 Level 4 or • ISO 16604 Class 5 or alternative equivalent set of standards	• AAMI PB70 (Level 1-3) • ASTM F3352 • EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O • AAMI PB70 Level 4 or ISO 16604 Class 5 or alternative equivalent set of standards
Particulate respirator				
Particulate respirator Good particle filtration (minimum 94% or	• N95 with/without respirator according to	Particulate respirator, grade N95 or higher i. Minimum "N95" respirator according to FDA	Fluid resistant respirator: • NIOSH 42 CFR 84, FDA minimum	**Fluid resistant respirator:** • NIOSH 42 CFR 84, FDA minimum

95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped), may be tested for fluid resistance (NIOSH/FDA surgical N95, EN 149 FFP2+Type IIR, GB 19083 Grade/Level 1)	US NIOSH or • FFP2 according to EN 149 or • KN95 according to China GB2626-2006 (Not affordable for level-1)	Class II, under 21 CFR 878.4040, and CDC NIOSH, or ii. Minimum "FFP2 according to EN 149, EU PPE iii. Regulation 2016/42 Category III, or equivalent	"surgical N95" • EN 149, minimum "FFP2" and EN 14683 Type IIR • GB 19083, minimum "Grade/Level 1", or alternative equivalent standard Non-fluid resistant respirator • NIOSH 42 CFR 84, minimum "N95" • EN 149, minimum "FFP2" • GB 2626, minimum "KN95" or alternative equivalent set of standard	"surgical N95" • EN 149, minimum "FFP2" and EN 14683 Type IIR • GB 19083, minimum "Grade/Level 1", or alternative equivalent standard **Non-fluid resistant respirator** • NIOSH 42 CFR 84, minimum "N95" • EN 149, minimum "FFP2" • GB 2626, minimum "KN95" or alternative equivalent set of standard
Mask				
Mask, medical healthcare worker Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance	• EN 14683 Type IIR Performance. • ASTM F2100 level 2 or level 3 or equivalent.	Mask, surgical-healthcare worker • EU MDD Directive 93/42/EEC Category III or equivalent • EN 14683 Type II, IR, IIR • ASTM F2100 minimum level 1 or equivalent.	Fluid resistant masks: • EN 14683 Type IIR, • ASTM F2100 Level 2 or 3, • YY 0469, with at least 98% bacterial droplet filtration, or alternative equivalent standard Non-fluid resistant mask: • EN 14683 Type II • YY/T 0969, with at least 98% bacterial droplet filtration, or alternative equivalent standard	**Fluid resistant masks:** • EN 14683 Type IIR, • ASTM F2100 Level 2 or 3, • YY 0469, with at least 98% bacterial droplet filtration, or alternative equivalent standard **Non-fluid resistant mask:** • EN 14683 Type II • YY/T 0969, with at least 98% bacterial droplet filtration, or alternative equivalent standard
Mask, medical patient. Medical mask, good breathability, internal and external faces		Mask, surgical-healthcare patient • EN 14683 any type including Type I • ASTM F2100	• EN 14683 Type I, • ASTM F2100 Level 1, • YY 0469 or YY/T 0969, if	• EN 14683 Type I, • ASTM F2100 Level 1, • YY 0469 or YY/T 0969, if bacterial droplet filtration is

should be clearly identified		minimum level 1 or equivalent	bacterial droplet filtration is below 98% or alternative equivalent standard.	below 98% or alternative equivalent standard.
Gloves				
Gloves, examination, non-sterile Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile. (e. g., minimum 230mm total length). Minimum thickness 0.05mm. Sizes S, M, L		Gloves, examination, non-sterile • EU MDD Directive 93/42/EEC Category III • EU PPE Regulation 2016/425 Category III • EN 455 • EN 374 • ANSI/ISEA 105, • ASTM D6319, or equivalent set of standards	• EN 455, • EN 374, optional additional: • ASTM D6319, D3578, D5250, D6977, or equivalent set of standards	• EN 455, • EN 374, • ANSI/ISEA 105 • ASTM D6319, D3578, D5250, D6977, or equivalent set of standards
Gloves, surgical, sterile Gloves, surgical, nitrile (preferable), latex, polyisoprene, or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10mm. Sizes ranging 5.0 - 9.0	• EN 455 • EN 374 • ANSI/ISEA 105-2011. • ASTM 6319	Gloves, examination or surgical, sterile EU MDD Directive 93/42/EEC Category III, • EU PPE Regulation 2016/425 Category III, • EN 455, • ANSI/ISEA 105, • ASTM D6319 or equivalent	• EN 455, • ASTM D3577, Sterility • United States Pharmacopeia, • EN ISO 11607, or alternative equivalent set of standards	• EN 455, • ASTM D3577, Sterility • United States Pharmacopeia, • EN ISO 11607, or alternative equivalent set of standards
Goggles				
Goggles, glasses protective Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure,	• EN 166/2002, • ANSI/ISEA Z87.1-2010.	**Goggles, protective** • EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1or equivalent	• EN 166, • ANSI/ISEA Z87.1, or alternative equivalent set of standards	• EN 166, • ANSI/ISEA Z87.1, or alternative equivalent set of standards

Enclose eyes and the surrounding areas. Accommodate wearers with prescription glasses. Clear plastic lens with fog and scratch resistant treatments. Adjustable band to secure firmly so as not to become loose during clinical activity. Indirect venting to avoid fogging. May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.				
Face Shield				
Made of clear plastic and providing good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog resistant (preferable). Completely cover the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	• EN 166/2002 • ANSI/ISEA Z87.1-2010	• EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1 or equivalent	• EN 166 (if reusable), or alternative equivalent set of standards	• EN 166 • ANSI/ISEA Z87.1 or alternative equivalent set of standards
Sanitizer (Alcohol-based hand rub)				
Alcohol-based hand rub		Bottle of 100 ml and 500 ml	Bottle of 100 ml and 500 ml, atleast 80% ethanol or 75% Isopropyl alcohol (v/v)	Matter outside the scope of MDB

Shoe Cover				
Shoe cover	PDMA recommended the same fabric and standard as that of medical gown or impervious non-porous polyethylene	No recommendations given by WHO vide their DCP	No recommendations given by WHO vide their DCP	No decision taken as no standard was given in WHO DCP
Long Shoes				
Long shoes		No recommendations given by WHO vide their DCP	No recommendations given by WHO vide their DCP	No decision taken as no standard was given in WHO DCP

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

In the previous meeting the following application was discussed:

"An application for Establishment License to import medical devices and productregistration namely UMV-001 EUA (Emergency Resuscitator) was forwarded by PEC. The following facts were noticed in the application:

i) The applicant was Umbulizer LLC based in USA, whereas it should be an authorized agent of the principal abroad based in Pakistan with an authorization letter;
ii) The applicant has an authorization agreement with M/s Ferozsons in Pakistan for marketing, so the application for product registration should come from M/s Ferozsons;
iii) M/s Ferozsons already got the Establishment License to import (ELI) medical devices therefore there is no need for application for ELI;
iv) The product UMV -001 EUA is an Emergency Resuscitator authorized by the FDA for Emergency Used Authorization (EUA) on 14-04-2020 under Public Health Emergency for COVID-19;
v) EUA is for a certain period and will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories during the COVID-19 pandemic is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act;
vi) The firm has applied for Clinical Trial for the said product. The information is available on clinicltrials.gov with the title "Evaluating safety and efficiency of Umbulizer in patients require Intermittent Positive Pressure Ventilation" with number NTC 0403028. The actual starting date was 04-09-2018 and the estimated primary completion date is 31-12-2020. The principal investigator is Dr. Kamran Cheema, Services Hospital."

The application for the aforementioned product has now been applied by M/s Ferozsons Pvt Ltd.

The matter is placed before the MDB for deliberation.

Decision:

1. **Medical Devices Board (MDB) considering that a product may be approved for enlistment / registration for import, if it is approved by the stringent regulatory authority including USA under sub-rule 2 of rule 15 of Medical Device Rules, 2017. Accordingly MDB approved / authorized UMV-001 EUA (Emergency**

Resuscitator) for its import and usage on similar terms and conditions as authorized by FDA under Emergency Use Authorization (EUA) (Annex-A).

2. **Moreover, the authorization for import and usage of product in Pakistan shall be terminated or revoked, if its authorization is terminated or revoked by FDA under EUA or in case any adverse event is observed in Pakistan.**
3. **Furthermore, keeping in view that emergency has not been declared in Pakistan, the authorization is subject to advice byNational Command & Operation Center (NCOC) whether the product under prevailing circumstances is required or not, when other alternatives (ventilators, CPAPs and BiPAPs) are available and number of COVID-19 patients is declining.**

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