

DECISIONS OF THE 23rd MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 04-11-2020

1. 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	National Electronics Complex of Pakistan	Address of Manufacturer: Plot 23, Street 6, Sector H-9/1, Islamabad. Manufacturing Site Address; A1 Lab NECOP, Plot 23, Street 6, Sector H-9/1, Islamabad.	Mr. Muhammad Ajmad (Biomedical Engineer) Production Incharge	Mr. Umair Hammad, Biomedical Engineer Quality Control Incharge.	
<p>Decision: The Board approved the grant of Establishment Licence to Manufacture Medical Devices to M/s National Electronics Complex of Pakistan, A1 Lab NECOP, Plot No. 23, Street 6, Sector H-9/1, Islamabad.</p>					
2	M/s Blitzkrieg Defense Solution Pvt. Ltd	Site Address: Plot No. 101-103, Humak Industrial Estate, Sihala Road, Islamabad	Mr. Kashif Khan (Pharmacist)	Mr. Burhan Uddin (Pharmacist)	
<p>Decision: The Board discussed the matter and decided to grant one month time to firm to re-organize their facility in accordance with lay out plan with proper flow of personnnel and materials as well as addresseing issues related to quality operations. Thereafter inspection be conducted by the panel and recommendations be placed before the MDB.</p>					

2. SITES VERIFICATION FOR ESTABLISHMENT OF MANUFACTURING UNITS OF MEDICAL DEVICES.

M/s SOS Technologies (Pvt) Limited, 1131-C, Mumtazabad, Multan (Site located at main NH 5 Bahawalpur Road, Mouza Gopal Pur, Near Lar, Multan has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at main NH 5 Bahawalpur Road, Mouza Gopal Pur, Near Lar, Multan.

Decision: The Board approved the site of M/s SOS Technologies (Pvt) Limited, 1131-C, Mumtazabad, Multan (Site located at main NH 5 Bahawalpur Road, Mouza Gopal Pur, Near Lar), Multan. The Board also observed that during site inspection, commitment be obtained from the firm for waste management in accordance with environment protection laws.

3. DEFERED CASES OF REGISTRATION/ENLISTMENT FOR IMPORT.

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description
1	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer: M/s Abbott Rapid Diagnostics, Jena GmbH., Orlaweg 1, 07743 Jena, Germany. FSC Germany COPY Issue Date 1-09-2020 (NOT Embassy attested)	Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal) Class C Code: Ref. 41FK10 Shelf Life: 12 Months (based on accelerated study results. The study is ongoing) Fee submitted: Rs. 50,000/-	Panbio COVID-19 Ag Rapid Test Device is an in vitro diagnostics rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio COVID-19 Ag Rapid Test Device is for professional use only and is

				<p>intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.</p> <p>The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions.</p> <p>Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.</p>
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Decision:- The firm has provided the required documents. The Board approved the product of the firm to be used in only in hospitals / institutions and clinical laboratories and also imposed condition of submitting quarterly safety/performance data to MDMC Division.

4. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE.

Smile Surgicals (Pvt) Ltd., HO: Plot No.06, Abbpara Housing Society Canal Road, Lahore 296-L, Street No.13, Industrial Estate, Gadoon Amazi, Dist Swabi (KPK)	Smile Disposable Syringes 1ml.3ml.5ml.10 ml.20ml. Class B Shelf Life: 03 Years Rs.20,000/-	Sterile Single Use Plastic Syringes	Approved 1ml, 10ml and 20 ml sizes subject to six months accelerated stability study data.
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Decision: The Board approved the request of the firm to grant additional sizes to manufacture 3ml and 5ml disposable syringes with condition that the firm shall observe the deadline of switching over from disposable syringes to Auto-disable syringes.

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