

BUREAU OF INDIAN STANDARDS

CHANDIGARH BRANCH OFFICE (CHBO)

Ref: CHBO/A-97002396

06/03/2023

Subject: All India first application for Certification as per IS/ISO 80601: PART 2: SEC 12:2011

CHBO has received an application from CARDIOLABS HEALTHCARE INDIA PRIVATE LIMITED for grant of licence for use of BIS Standard Mark on the product MEDICAL ELECTRICAL EQUIPMENT PART 2-12 PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF CRITICAL CARE VENTILATORS as per IS/ISO 80601: PART 2: SEC 12:2011 under Normal Procedure for Grant of Licence.

As per the information obtained from BIS Website/ Intranet, Circulars of CMD's to ROs/ BOs the following is observed:

1. No BIS licence exists for the aforementioned product.
2. Marking fee, SIT & Grouping guidelines are not available for the product.
3. No approved testing facility (BIS Labs or OSL) is available for this product.

In the view of above, the application may be considered as All India first application for Certification for the above product.

CMD-III and all ROs/BOs/Labs are requested to send any information with respect to the above IS or any other information which may be helpful to process this application.

LPPD/LRMD is requested to confirm the availability of complete testing facilities & testing charges as per IS/ISO 80601: PART 2: SEC 12:2011.

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Scientist - C

Sc. F & HEAD(CHBO)

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H(CMD-III)

All ROs and BOs

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