

BUREAU OF INDIAN STANDARDS
(Chandigarh Branch Office)

Our Reference: CHBO/ IS/ISO 80601-2-12 : 2011/ A-97000998

Dated:11/02/2020

1. CHBO has received an application under Normal Procedure for Grant of Licence to use Standard Mark on the product ‘ Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 12 Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators as per IS/ISO 80601-2-12 : 2011.
2. As per the information obtained from BIS website, circulars and HO/RO queries:
 - (a) As on date, no BIS licence exists for the mentioned product.
 - (b) As on date, no other BIS application is pending for the aforementioned product.
 - (c) Marking Fee and SIT are not available for the product.
 - (d) No BIS, or BIS approved lab has testing facility as per IS/ISO 80601-2-12 : 2011.
3. Therefore, this application may be considered to be All India First Application for the above product.
4. CMD-3, LPPD and all ROs & BOs are, therefore, requested to provide any information with respect to the above IS or any other information which may be useful to process the application. ITSD is requested to host the information pertaining to the above application on intranet.

(Deepak Kumar)

Scientist C,
CHBO

Scientist.-F & Head (CHBO)

DDGN

Head (CMD-3)

Head (LPPD)

ITSD- with a request for circulation on intranet