

भारतीय मानक ब्यूरो

(लखनऊ शाखा कार्यालय)

हमारा संदर्भ : ल.शा.का./IS/IEC 80601-2-49: 2018

15 नवम्बर 2023

विषय : अखिल भारतीय स्तर पर IS/IEC 80601-2-49: 2018 बी.आई.एस. प्रमाणन प्राप्त करने के लिए सर्वप्रथम आवेदन के सम्बन्ध में।

लखनऊ शाखा कार्यालय में IS/IEC 80601-2-49: 2018 पर बी.आई.एस. प्रमाणन प्राप्ति हेतु अखिल भारतीय स्तर पर सर्वप्रथम आवेदन प्राप्त हुआ है। इस सम्बन्ध में विस्तृत जानकारी संलग्नक नोट में प्रदान किया गया है जो सभी के अवलोकनार्थ इंटरनेट पर होस्ट किया जा रहा है।

प्रणय जैन

(प्रणय अभय जैन)

वैज्ञानिक - बी

असित
15/11/2023

प्रमुख, ल.शा.का.

Bureau of Indian Standards
Lucknow Branch Office

Date-15th Nov 2023

Our Ref: LKBO/IS/IEC 80601-2-49: 2018

Subject: All India First Application as per IS/IEC 80601-2-49: 2018

LKBO has received an application under Normal Procedure for Grant of Licence to use of BIS Standard Mark on the product “**Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 49 Multifunction patient monitors**” as per **IS/IEC 80601-2-49: 2018**

As per the information gathered from BIS Website, circulars of CMD's to ROs/ BOs the following are observed with respect to **IS/IEC 80601-2-49: 2018**:

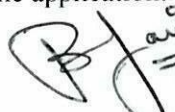
1. As on date, no BIS licence exists for the product.
2. As on date, no other BIS application is pending for the product.
3. Marking fee, SIT & grouping guidelines are not available for the product.
4. As per LIMS portal, no test facility exists at any BIS Lab/ BIS recognized labs.


Therefore, this application may be considered to be **All India First Application** for the above product.

CMD-3 is requested to provide us with relevant grouping guidelines, SIT, Marking fee, if any prevailing for this product.

LPPD and LRMD is also requested to provide details regarding possible BIS labs/BIS Recognized or Empanelled labs/Other labs who can undertake testing for the mentioned product as presently test facility is not available, as per data on website.

All ROs and BOs are also requested to send information regarding the above product with respect to any application at their end or any other information which may be helpful to process the application.


15.11.23
Jain Pranay Abhay
Sc-B/ Assistant Director

Head(LKBO) 
15/11/2023

DDGC/DDG(cert)/Head(CMD 3)/Head (LPPD)/Head (LRMD)/Head (MHD)/All ROs/ All BOs

ITS- with request for circulation on intranet