

Bureau of Indian Standards

Our Ref: FMCD/A- 4102879

06/07/2022

Subject: First application for Certification for GoL as per IS 13452 : Part 2: Sec 47 : 2018

FMCD has received an application from M/s. Dreamtech Co. Ltd., South Korea for grant of licence for use of BIS Standard Mark on the product Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 47 ambulatory electrocardiographic systems as per IS 13452 : Part 2: Sec 47 : 2018

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 above mentioned product.
2. Marking fee, SIT & Grouping guidelines are not available for the product.
3. No test facility available.

In the view of above, the application may be considered as First application for Certification for the above product.

CMD-3 is requested to provide SIT, marking fee, or any other information prevailing for this product on priority.

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

All labs/ LPPD/LRMD is requested to confirm the availability of testing facilities & testing charges as per IS 13452 : Part 2: Sec 47: 2018

Sachin
06/07/2022
(Sachin Choudhary)
Scientist - C, FMCD

[Signature]
11/07
Head (FMCD)
DDG(FMCD, Reg.& MCSD)
Head (CMD-3)
Head (LPPD)
Head (LRMD)
All RO's & BO's
ITSD- For circulation on intranet

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