

Bureau of Indian Standards

Our Ref: FMCD/A- 4104603

02/02/2024

Subject: First application for Certification for GoL as per IS/ISO 80601: Part 2: Sec 61: 2011

FMCD has received an application from M/s Murata Vios Pvt. Ltd Japan for grant of licence for use of BIS Standard Mark on the product Medical Electrical Equipment Part 2 Particular Requirements of the Basic safety and Essential Performance Section 61 Pulse Oximeter Equipment as per IS/ISO 80601: Part 2: Sec 61: 2011.

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. Test facility exists at BIS Approved OSL (M/s TUV Rheinland (India) Pvt. Ltd., Visakhapatnam

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.

(Singaraju Venkatesh)
Scientist - C, FMCD

Head (FMCD)