

केन्द्रीय मुहर विभाग - III

हमारा संदर्भ- केन्द्रीय मुहर विभाग-III/16: आई एस 13450(भाग 2/अनुभाग 25) 4 जनवरी 2021

विषय: प्रोडक्ट मैनुअल - एसआईटी एवं ग्रुपिंग गाइडलाइंस के साथ

सभी शाखा कार्यालय से आग्रह है कि उपरोक्त विषय से संबंधित संलग्न परिपत्र का अवलोकन करें।

(ऐ के कअंर)
वैज्ञानिक-सी (सी एम् डी-III)

प्रमुख (सी एम् डी-III)

सभी क्षेत्रीय/शाखा कार्यालय

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-III/16: IS 13450 (Pt 2/ Sec 25)

4 Jan 2021

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Pt 2/ Sec 25):2018

BOs may kindly see the attached circular on the subject mentioned above.

(A K Kanar)
Sc-C (CMD III)

Head (CMD - III)

Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-III/16: IS 13450 (Pt 2/ Sec 25)

4 Jan 2021

Subject: Product Manual incorporating SIT and Grouping Guidelines for Medical Electrical Equipment: Particular Requirements for the Basic Safety and Essential Performance – Electrocardiographs as per IS 13450 (Pt 2/ Sec 25):2018

This has reference to the subject mentioned above.

The approved Product Manual for **IS 13450 (Pt 2/ Sec 25):2018 - Specification for ‘Medical Electrical Equipment: Particular Requirements for the Basic Safety and Essential Performance - Electrocardiographs’** has been hosted on the BIS website under

“Conformity Assessment → Product Certification → Product Specific Guidelines → Product Manual.

BOs are advised to send this Product Manual, which incorporates Grouping Guidelines and SIT to all licensee/applicants immediately. The SIT, which has been incorporated in the Product Manual, shall be implemented **with immediate effect.**

(A K Kanar)
Sc-C (CMD III)

Head (CMD III)
DDG (Certification)

Circulated to: All ROs/BOs