

केन्द्रीय मुहर विभाग - III

हमारा संदर्भ- केन्द्रीय मुहर विभाग-III/16: IS 13450-2-25

18 अक्टूबर 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।

(जे एस कविन कीर्थी विनायगम)
वैज्ञानिक 'सी' (सी एम डी-III)

प्रमुख (सी एम डी-III)

सभी क्षेत्रीय/शाखा कार्यालय

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-III/16: IS 13450-2-25

18 October 2021

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2/ Sec 25): 2018/ IEC 60601-2-25: 2011

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

(JS Kavin Keerthy Vinayagam)
Scientist-C (CMD III)

Head (CMD - III)

Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-III/16: IS 13450-2-25

18 October 2021

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2/ Sec 25): 2018/ IEC 60601-2-25: 2011

This has reference to the subject mentioned above.

The approved Product Manual for **IS 13450 (Part 2/ Sec 25): 2018/ IEC 60601-2-25: 2011 - 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**.

(JS Kavin Keerthy Vinayagam)
Scientist-C (CMD III)

Head (CMD III)

DDG (Certification)

Circulated to: All ROs/BOs