

केन्द्रीय मुहर विभाग - III

हमारा संदर्भ- के. मु. वि. - III/16: IS 13450 (भाग 2 / अनुभाग 44)

22 अक्टूबर 2022

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।

(पीयूष प्रकाश)
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 (Part 2/ Sec 44)

22 October 2022

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2/ Sec 44) : 2016 / IEC 60601-2-44 : 2009- 'MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 44 X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY (FIRST REVISION)'

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

(Peeyush Prakash)
Sc-C (CMD III)

Head (CMD - III)

Circulated to: All ROs/BOs

CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-III/16: IS 13450 (Part 2/ Sec 44)

22 October 2022

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2/ Sec 44) : 2016 / IEC 60601-2-44 : 2009- 'MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 44 X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY (FIRST REVISION)'

This has reference to the subject mentioned above.

The approved revised Product Manual for **IS 13450 (Part 2/ Sec 44) : 2016 / IEC 60601-2-44 : 2009- 'MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 44 X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY (FIRST REVISION)'** has been hosted on the BIS website under

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

The revised product manual includes modifications in product name, scope of licence, grouping guideline, and SIT.

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

(Peeyush Prakash)
Sc-C (CMD III)

Head (CMD III)
DDG (Certification)

Circulated to: All ROs/BOs