

## केन्द्रीय मुहर विभाग - III

हमारा संदर्भ - के. मु. वि. - III/ 6: आई एस 13450 (भाग 2 / अनु. 37)

29 अगस्त 2023

विषय: प्रोडक्ट मैनुअल - एसआईटी एवं ग्रुपिंग गाइडलाइंस के साथ आई एस 13450 (भाग 2 / अनुभाग 37) : 2019 / आईईसी 60601-2-37 : 2007 "चिकित्सीय विद्युत् उपस्कर भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष आवश्यकताएं अनुभाग 37 अल्ट्रासोनिक चिकित्सा नैदानिक और निगरानी उपकरण" के लिए

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

पीयूष प्रकाश  
वैज्ञानिक डी (सी एम डी-III)

### प्रमुख (सी एम डी-III)

सभी क्षेत्रीय/शाखा कार्यालय  
आई टी एस विभाग — बीआईएस इंटरनेट पर अपलोड करने हेतू

## CENTRAL MARKS DEPARTMENT-III

Our Ref: CMD-III/16: IS 13450 (Part 2/ Sec 37)  
2023

29 August

**Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2 / Sec 37) : 2019 / IEC 60601-2-37 : 2007 'Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 37 - Ultrasonic medical diagnostic and monitoring equipment'**

Circular on the above subject is being issued for information to all concerned.

Peeyush Prakash  
Sc-D (CMD III)

### Head (CMD - III)

Circulated to: All concerned for information

Copy to: ITSD for hosting on BIS website under "What's New" Tab

**CENTRAL MARKS DEPARTMENT – III**

**Our Ref: CMD-III/16: IS 13450 (Part 2/ Sec 37)**

**29 August 2023**

**Subject: Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2 / Sec 37 ): 2019 / IEC 60601-2-37 : 2007 ‘Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 37 - Ultrasonic medical diagnostic and monitoring equipment’**

This has reference to the subject mentioned above.

The approved **Product Manual incorporating SIT and Grouping Guidelines for IS 13450 (Part 2 / Sec 37 ): 2019 / IEC 60601-2-37 : 2007 ‘Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 37 - Ultrasonic medical diagnostic and monitoring equipment’** has been hosted on the BIS website under

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

The product manual includes 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 applicants immediately. The SIT which has been incorporated in the Product Manual shall be implemented with immediate effect.

Peeyush Prakash  
Sc-D (CMD III)

**Head CMD-III**

**Circulated to:** All concerned for information

**ITSD –** With a request to host the details on BIS website under “What’s New” Tab.