

केन्द्रीय मुहर विभाग - III

हमारा संदर्भ - के. मु. वि.- III/ 16: आई एस/आईईसी 80601-2-58
विषय: प्रोडक्ट मैनुअल - एसआईटी एवं ग्रुपिंग गाइडलाइंस के साथ

20 जनवरी 2023

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

पीयूष प्रकाश
वैज्ञानिक सी (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/ IEC 80601-2-58

20 January 2023

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS/IEC 80601-2-58 : 2016 'Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 58 Lens removal devices and vitrectomy devices for ophthalmic surgery'

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

Peeyush Prakash
Sc-C (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/ IEC 80601-2-58

20 January 2023

Subject: Product Manual incorporating SIT and Grouping Guidelines for IS/IEC 80601-2-58 : 2016 ‘Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 58 Lens removal devices and vitrectomy devices for ophthalmic surgery’

This has reference to the subject mentioned above.

The approved revised Product Manual for **Product Manual incorporating SIT and Grouping Guidelines for IS/IEC 80601-2-58 : 2016 ‘Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 58 Lens removal devices and vitrectomy devices for ophthalmic surgery’** 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