<u>केन्द्रीय महुर विभाग - III</u>

हमारा संदर्भ - केन्द्रीय महुर विभाग - III/16 : IS/ISO 80601 (Part 2/ Sec 61)

03 जुलाई 2024

विषय : प्रोडक्ट मैन्युअल आईएस/आईएसओ : 80601 (भाग 2 / खंड 61) : 2017

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

(राहुल विश्वकर्मा) वैज्ञानिक – सी (सी एम डी – III)

प्रमुख (सी एम डी – III) सभी क्षेत्रीय / शाखा कार्यालय

<u>CENTRAL MARKS DEPARTMENT – III</u>

Our Ref: CMD-III/16: IS/ISO 80601 (Part 2 / Sec 61)

03 July 2024

Subject: Product Manual for IS/ISO 80601 (Part 2 / Sec 61): 2017– Medical Electrical Equipment – Part 2 – Particular Requirements for Basic Safety and Essential Performance – Sec 61 Pulse Oximeter Equipment.

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

(Rahul Vishwakarma) Sc-C (CMD-III)

Head (CMD-III)

Circulated to: All ROs/BOs

<u>CENTRAL MARKS DEPARTMENT – III</u>

Our Ref: CMD-III/16: IS/ISO 80601 (Part 2 / Sec 61) 03 July 2024

Subject: Product Manual for IS/ISO 80601 (Part 2 / Sec 61): 2017– Medical Electrical Equipment

- Part 2 - Particular Requirements for Basic Safety and Essential Performance - Sec 61

Pulse Oximeter Equipment

This has reference to the subject mentioned above.

The Product Manual for IS/ISO 80601 (Part 2 / Sec 61): 2017— Medical Electrical Equipment — Part 2 — Particular Requirements for Basic Safety and Essential Performance — Sec 61 Pulse Oximeter Equipment 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 and applicants immediately.

(Rahul Vishwakarma) Sc-C (CMD-III)

Head (CMD-III)

DDG (Certification)

Circulated to: All ROs/BOs