

Email

MHD BIS

Fwd: DRAFT Email - Approval of Documents for Publication as Indian Standards**From :** Head MHD BIS <hmhd@bis.gov.in>

Mon, Dec 04, 2023 10:38 AM

Subject : Fwd: DRAFT Email - Approval of Documents for Publication as Indian Standards**To :** MHD BIS <mhd@bis.gov.in>**From:** shekharc57@yahoo.com**To:** "Head MHD BIS" <hmhd@bis.gov.in>**Sent:** Monday, December 4, 2023 10:22:31 AM**Subject:** Re: DRAFT Email - Approval of Documents for Publication as Indian Standards

Approved
Chander Shekhar

Sent from my iPhone

On 01-Dec-2023, at 6:32 PM, Head MHD BIS <hmhd@bis.gov.in> wrote:

Respected Sir,

The final proofs for the following documents have been received from Publications department, BIS :

S.No.	Document Number	Designation	Title
1.	MHD/15/226/60	IS 18448 (Part 1) : 2023	Medical electrical equipment Diagnostic X-rays Part 1 Determination of quality equivalent filtration and permanent filtration
2.	MHD/15/226/55	IS 13450 (Part 1/Sec 9) : 2023	Medical electrical equipment Part 1 General requirements for basic safety and essential performance Section 9 Requirements for environmentally conscious design
3.	MHD/15/226/48	IS 13450 (Part 1) : 2023 IEC 60601-1 : 2020	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance (Third Revision)

4.	MHD/ 15/226 68	IS 13450 (Part 2/Sec 45) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 45 Mammographic X-ray equipment and mammographic stereotactic devices (Second revision)
5.	MHD/ 15/226 63	IS 18470 : 2023	Ultrasonics Physiotherapy Systems Field Specifications and Methods of Measurement in the Frequency Range 05 MHz to 5 MHz
6.	MHD/ 15/226 71	IS 13450 (Part 2/Sec 65) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 65 Dental intra-oral X-ray equipment (First revision)
7.	MHD/ 15/226 58	IS 13450 (Part 1/Sec 12) : 2023	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 12 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
8.	MHD/ 15/226 53	IS 13450 (Part 1/Sec 6) : 2023	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 6 Usability (First revision)
9.	MHD/ 15/226 66	IS 13450 (Part 2/Sec10) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 10 Nerve and muscle stimulators (First revision)
10.	MHD/ 15/226 61	IS 18448 (Part 2) : 2023	Medical electrical equipment Diagnostic X- rays Part 2 Guidance and rationale on quality equivalent filtration and permanent filtration
11.	MHD/ 15/226 56	IS 13450 (Part 1/Sec	Medical electrical equipment : Part 1 General requirements for basic safety and essential

		10) : 2023	performance, Section 10 Requirements for the development of physiologic closed-loop controllers (First Revision)
12.	MHD/ 15/226 69	IS 13450 (Part 2/Sec 54) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 54 X-ray equipment for radiography and radioscopy (First revision)
13.	MHD/ 15/226 51	IS 13450 (Part 1/Sec 2) : 2023	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 2 Electromagnetic disturbances Requirements and tests (Second Revision)
14.	MHD/ 15/226 64	IS 13450 (Part 2/Sec 2) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 2 High frequency surgical equipment and high frequency surgical accessories (First revision)
15.	MHD/ 15/226 59	IS 18443 : 2023	Medical electrical equipment X-ray tube assemblies for medical diagnosis Focal spot dimensions and related characteristics
16.	MHD/ 15/226 79	IS 11789 : 2023	Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis (First Revision)
17.	MHD/ 15/226 54	IS 13450 (Part 1/Sec 8) : 2023	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 8 General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (First Revision)
18.	MHD/ 15/226 67	IS 13450 (Part 2/Sec	Medical electrical equipment Part 2 Particular requirements for basic safety and essential

		43) : 2023	performance Section 43 X-ray equipment for interventional procedures (Second revision)
19.	MHD/ 15/226 62	IS/IEC 61675-1: 2022	Radionuclide imaging devices Characteristics and test conditions Part 1 Positron emission tomographs (First Revision)
20.	MHD/ 15/226 57	IS 13450 (Part 1/Sec 11) : 2023	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance , Section 11 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (First Revision)
21.	MHD/ 15/226 52	IS 13450 (Part 1/Sec 3) : 2023	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 3 Radiation protection in diagnostic X-ray equipment (First Revision)
22.	MHD/ 15/226 70	IS 13450 (Part 2/Sec 63) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 63 Dental extra-oral X-ray equipment (First revision)
23.	MHD/ 15/226 65	IS 13450 (Part 2/Sec 3) : 2023	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 3 Short-wave therapy equipment (First revision)

In accordance with Sub-rule (5) of Rule 22 of the BIS Rules 2018 , copies of the documents mentioned above as finalized by Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee, MHD 15 and authorized by the Chairperson, in the light of comments received from important producers, consumers, technologists, members of Medical Equipment & Hospital Planning Division Council is attached.

Your approval for adoption of the attached documents as Indian Standards on behalf of MHDC may kindly be sent as reply to this email.

A copy of the authorization by the Chairperson of the respective Sectional Committee is also attached.

With thanks and regards,

A R Unnikrishnan,
Scientist-F and Head(MHD)



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