

चिकित्सा उपकरण एवं अस्पताल नियोजन विभाग
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPT

संदर्भ/Ref: एम.एच.डी 19/ ए - 6; MHD 19/A6

दिनांक: 15.03.2021

विषय/Sub: एम.एच.डी 19 के भारतीय मानकों की पुनः पुष्टि / Reaffirmation of Indian Standards of MHD 19

निम्नलिखित भारतीय मानकों की 'इन्विट्रो डायग्नोस्टिक मेडिकल डिवाइसेस का जैविक मूल्यांकन विषय समिति एम.एच.डी 19' द्वारा पांच साल की अवधि के लिए फिर से पुष्टि की गई है, जैसा कि नीचे सूची में दिया गया है :


The Indian Standards listed below have been reaffirmed by **Biological Evaluation of Invitro Diagnostic Medical Devices Sectional Committee, MHD 19** *w.e.f* the dates indicated in the table below for a further period of five years as indicated below:

S No	IS No	Title	Due Date
1.	IS 12572: Part 1: 1994	Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests	February 2021
2.	IS 12572: Part 2: 1995	Biological evaluation of medical devices: Part 2 animal welfare requirements	February 2021
3.	IS 12572: Part 3: 1988	Guide for evaluation of medical devices for biological hazards: Part 3 method of testing by tissue implantation	February 2021
4.	IS 12572: Part 5: 1988	Guide for evaluation of medical devices for biological hazards: Part 5 method of test for intracutaneous reactivity of extracts from medical devices	February 2021
5.	IS 12572: Part 6: 1988	Guide for evaluation of medical devices for biological hazards: Part 6 method of test for systemic toxicity: assessment of pyrogenicity in rabbits of extracts from medical devices	February 2021
6.	IS 12572: Part 7: 1988	Guide for evaluation of medical devices for biological hazards: Part 7 methods of test for sensitization: assessment of potential of medical devices to produce delayed contact dermatitis	February 2021
7.	IS 12572: Part 8: 1988	Guide for evaluation of medical devices for biological hazards: Part 8 method of test for skin irritation of extracts from medical devices	February 2021
8.	IS 12572: Part 9: 1988	Guide for evaluation of medical devices for biological hazards: Part 9 method of	February 2021

		test for skin irritation by solid medical devices	
9.	IS 12572: Part 11: 1990	Guide for evaluation of medical devices for biological hazards: Part 11 method of test for eye irritation	February 2021

Director (Sales)/DPT/D (PUB)/DLSC may kindly take suitable action for affixing the year of re-affirmation to these Indian Standards.

निदेशक (बिक्री) /डी(पीयूबी)/ डी(एलएससी) से अनुरोध है की वे उपरोक्त भारतीय मानकों पर पुनःपुष्टिकरण के वर्ष की स्थापना के लिए उचित कार्यवाही करें।


(पी वी मैथ्यू)

प्रमुख (आई टी एस)

वैज्ञानिक 'इ' एवम् प्रमुख (एम.एच.डी)

D (Sales)
DPT
D (PUB)
DLSC

Copy to:

- i) All Regional Offices
- ii) All Branch Offices
- iii) All Inspection Offices
- iv) All Technical Departments in HQ
- v) All Labs
- vi) ITS Dept. - with the request to upload the information on BIS intranet

All by email