सत्यमेव जयते

मानकः पथप्रदर्शकः

# BUREAU OF INDIAN STANDARDS

*(Government of India, Ministry of Consumer Affairs, Food and Public Distribution)*

**Medical Equipment and Hospital Planning Department**

## Webinar on
## "*In-Vitro* Diagnostic Medical Devices: Standardization and Regulation"

**Date:** 09 February 2022
**Time:** 1000 h

सत्यमेव जयते

मानकः पथप्रदर्शकः

Greetings from BIS!

Bureau of Indian Standards (BIS), the National Standards Body (NSB) of India, formulates standards in various sectors including Medical Devices. BIS has formulated more than 1400 Indian Standards for Medical Devices through Medical Equipment and Hospital Planning Department (MHD). *In-Vitro* Diagnostic Medical Devices Sectional Committee MHD 19 formulates standards for Reagents, kits and Instruments.

Diagnostics industry has witnessed tremendous growth in recent times. *In-vitro* diagnostic Medical Devices has played an indispensable role in combatting the COVID-19 battle.

This webinar organized by Medical Equipment and hospital planning department (MHD) of BIS, covers the entire life cycle of *In-Vitro* Diagnostic Medical Devices with special emphasis on National Standards, Regulations, testing and validation.

**Target Audience**:

- *In-Vitro* Diagnostic Medical Device Manufacturers
- Academicians
- Regulatory Affairs and R&D Product Development Manager
- Clinicians

**Link for Registration**:

**Register**

सत्यमेव जयते

मानकः पथप्रदर्शकः

## Agenda Items

| *Session* | *Topic of the Lecture* | *Speaker* |
|---|---|---|
| ***Inaugural Session*** | | |
| **1000 – 1010 h** | Welcome Address and Objectives of the Seminar | Shri. P. V. Mathew,<br>Scientist E, Head (MHD) |
| **1010 – 1020 h** | Opening Remarks | Shri Jayanta Roy Chowdhury,<br>Scientist-G & DDG (Standardization-I) |
| **1020 – 1030 h** | Keynote address | Dr. Reba Chhabra,<br>Chairperson of *In-Vitro* Diagnostic Medical Devices Sectional Committee MHD 19,<br>In personal Capacity,<br>Former Director In-Charge,<br>National Institute of Biologicals (NIB) |
| ***Technical Session*** | | |
| **1030 – 1050 h** | Regulatory Framework for *In-Vitro* Diagnostic Medical Devices in India | Dr. Ravi Kant Sharma,<br>Deputy Drug Controller of India,<br>The Central Drugs Standard Control Organization (CDSCO) |
| **1050 – 1110 h** | Global Scenario of *In-Vitro* Diagnostic Medical Device Regulation | Dr. Harish Chander,<br>Divisional Head,<br>The National Institute of Biologicals (NIB), Noida. |
| **1110 – 1130 h** | Indian *In-Vitro* Diagnostic Medical Device Industry: at a point of inflection | Ms. Veena Kohli,<br>President of Association of Diagnostics Manufacturers of India (ADMI) & CEO & Founder, Vanguard Diagnostics (P) Ltd. |
| **1130 – 1140 h** | Indian Standards for *In-Vitro* Diagnostic Medical Devices | Ms. Nagavarshini M.,<br>Scientist B, MHD BIS. |
| **1140 – 1150 h** | Q & A Session | |
| **1150 – 1200 h** | Vote of Thanks | Ms. Nagavarshini M.,<br>Scientist B, MHD BIS. |

**For more information visit BIS Website**:
https://www.manakonline.in/MANAK/login
https://www.bis.gov.in/