



Certificate No. MD-QMS/91/R/II/2559/d

This is to certify that

EON MEDITECH PRIVATE LIMITED

**Registered Office : Plot No. 12, Gurukrupa Society, Opp. Utran Arogya Kendra,
Utran Road, Utran, Surat - 394 105, Gujarat, India**

(a list of certified workplaces is contained in Annexure which is inseparable part of this Certificate)

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope :

Design, Development, Manufacture and Sales of Otology Implants, Ear Ventilation Tubes, Medical PVA Dressings, Gelatin Sponges, Nasal Splints, Septal Buttons, Silicone Sheetings, Laryngeal Tubes, Esophageal Tubes, Laryngeal Buttons, Laryngeal Keels, Laryngeal Stents, Tracheal Tubes, Thoracic T-Tubes, Salivary Bypass Tubes, Speaking Valves, Voice Prosthesis and its relevant Accessories, Plasma Wand System, Tracheal Stents, ENT Burs, ENT Blades, ENT Suction Tubes and ENT Instruments.

Initial Certification : 10/10/2012
Re-certification : 28/10/2021
Valid until : 09/10/2024



Authorised Signatory

The authenticity of this document may be re-affirmed by writing to certification@zenith-worldwide.com. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.

Accreditation Body: International Accreditation Service, Inc.
3060 Saturn Street, Suite 100, Brea, California 92821-1732 U.S.A
www.iasonline.org

Issuing Authority: Zenith Quality Assessors Pvt. Ltd.
Office No. 01A, B-Wing, Siddhesh OPTIMUS, S. No. 211,
Viman Nagar, Pune – 411 014, Maharashtra, India
www.zenith-worldwide.com



Annexure to Certificate No. MD-QMS/91/R/1/2559/d

Issued to the Company

EON MEDITECH PRIVATE LIMITED

Scope of Certification :

Design, Development, Manufacture and Sales of Otology Implants, Ear Ventilation Tubes, Medical PVA Dressings, Gelatin Sponges, Nasal Splints, Septal Buttons, Silicone Sheetings, Laryngeal Tubes, Esophageal Tubes, Laryngeal Buttons, Laryngeal Keels, Laryngeal Stents, Tracheal Tubes, Thoracic T-Tubes, Salivary Bypass Tubes, Speaking Valves, Voice Prosthesis and its relevant Accessories, Plasma Wand System, Tracheal Stents, ENT Burs, ENT Blades, ENT Suction Tubes and ENT Instruments.

Workplaces and Scope of Activities :

Registered Office : Plot No. 12, Gurukrupa Society, Opp. Utran Arogya Kendra, Utran Road, Utran, Surat - 394 105, Gujarat, India

Scope of Activities : Management, Human Resource, Marketing and Sales

Works : BL 54, 127, 129, Khanpur Road, Mirapur, Kamrej, Surat - 394 320, Gujarat, India

Scope of Activities : Management, Purchase, Design and Development, Production, Quality Control, Stores and Dispatch

Initial Certification : 10/10/2012

Re-certification : 28/10/2021

Valid until : 09/10/2024



Authorised Signatory