



Certificate No. MD-QMS/91/R/N/3064

This is to certify that

AMTECH MEDIDEVICES PRIVATE LIMITED

Corporate Office : Flat No. 03, 7-C, First Floor, Shantsagar Hotels Pvt. Ltd., Tadiwala Road, Near Panchratna Hotel, Pune – 411 001, Maharashtra, 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 and Development, Manufacture and Sales of Non-sterile, Non-active, Non-implantable Medical Devices: Orthopedic and General Surgical Instruments**
- **Manufacture and Sales of Non-sterile, Non-active, Implantable Medical Devices: Customized 3D Printed Orthopedic Implants, Cranio-maxillofacial Implants and related Jigs and Guides**

Technical Area/s (Ref. IAF MD9) :

A.1.1

Initial Certification : 14/06/2025
Valid until : 13/06/2028



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: National Accreditation Board for Certification Bodies (NABCB)
Quality Council of India (QCI), 2nd Floor, Institution of Engineers Building, Bahadur Shah Zafar Marg,
New Delhi – 110 002, India
www.nabcb.qci.org.in

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/N/3064**

Issued to the Company

AMTECH MEDIDEVICES PRIVATE LIMITED

Scope of Certification :

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- Manufacture and Sales of Non-sterile, Non-active, Implantable Medical Devices: Customized 3D Printed Orthopedic Implants, Cranio-maxillofacial Implants and related Jigs and Guides

Workplaces and Scope of Activities :

Corporate Office : Flat No. 03, 7-C, First Floor, Shantsagar Hotels Pvt. Ltd., Tadiwala Road,
Near Panchratna Hotel, Pune – 411 001, Maharashtra, India

Scope of Activities : Legal

Manufacturing Site : Plot No. W-110, S Block, MIDC Bhosari, Pune – 411 026, Maharashtra, India

Scope of Activities : Management, Human Resource, Marketing & Sales, Purchase,
Design & Development, Regulatory Affairs, Production, Quality Assurance,
Quality Control, Stores & Dispatch

Initial Certification : 14/06/2025
Valid until : 13/06/2028

