



**EA MLA Signatory**  
**Český institut pro akreditaci, o.p.s.**  
(Czech Accreditation Institute)  
**Hájkova 2747/22, Žižkov, 130 00 Praha 3**

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products and on changes and amendments to some Acts, as amended

# CERTIFICATE OF ACCREDITATION

No. 63/2026

**Český metrologický institut**  
**with registered office Okružní 31, 638 00 Brno**  
**Company Registration No. 00177016**

for the Certification Body No. 3266  
Certification Body of the Czech Metrology Institute for the Certification of Management Systems

Scope of accreditation:

Certification of a medical device quality management system in accordance with ISO 13485 (QMS-MD) to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

**ČSN EN ISO/IEC 17021-1:2016**

In its activities performed within the scope and for the period of validity of this Certificate, the abovementioned Accredited Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited conformity assessment body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 679/2024 of 16/12/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **16/12/2027**

Prague: 10/02/2026



Signed in the Czech original:  
Tomáš Mikuta on 10/02/2026

**Tomáš Mikuta**  
Director of the Department  
of Certification and Inspection Bodies  
Czech Accreditation Institute

This translation of the Czech original has been issued by: Andrea Muzikářová

**The Appendix is an integral part of  
Certificate of Accreditation No. 63/2026 of 10/2/2026**

**Accredited entity according to ČSN EN ISO/IEC 17021-1:2016:**

**Český metrologický institut**

CAB number 3266, Certification Body of the Czech Metrology Institute for the Certification of  
Management Systems

Hvožd'anská 2053/3, 148 00 Praha - Chodov

**1. Certification of Quality Management Systems for the provision of medical devices  
and related services (QMS-MD)**

<b>Ordinal number</b>	<b>Main Technical Areas / Technical Areas<sup>1</sup></b>	<b>Specification of standards (normative documents)</b>
1.	1. Non-active Medical Devices	ČSN EN ISO 13485 ed. 2:2016 ISO 13485:2016 EN ISO 13485:2016
	1.1. General non-active, non-implantable medical devices	
	1.2. Non-active implants	
	1.3. Devices for wound care	
	1.4. Non-active dental devices and accessories	
2.	2. Active (non-implantable) medical devices	ČSN EN ISO 13485 ed. 2:2016 ISO 13485:2016 EN ISO 13485:2016
	2.1. General active medical devices	
	2.2. Devices for imaging	
	2.3. Monitoring devices	
3.	2.4. Devices for radiation therapy and thermo therapy	ČSN EN ISO 13485 ed. 2:2016 ISO 13485:2016 EN ISO 13485:2016
	5. Sterilization methods for medical devices	
	5.1. Ethylene oxide gas sterilization (EOG)	
4.	5.5. Low temperature steam and formaldehyde sterilisation	ČSN EN ISO 13485 ed. 2:2016 ISO 13485:2016 EN ISO 13485:2016
	7. Parts and services	
	7.2. Components	
	7.3. Subassemblies	
	7.4. Calibration services	
	7.5. Distribution services	
7.6. Maintenance		

<sup>1</sup> according to Annex 1 Scope of Accreditation of IAF MD 8:2023

---

*"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself. "*