

CERTIFICATE OF ACCREDITATION

No. Q-084

dated 08.12.2023

The Slovak National Accreditation Service issues a Certificate of Accreditation to an accredited body pursuant to Section 26 par.6 of Act No. 53/2023 Coll. on Accreditation of Conformity Assessment Bodies (hereinafter referred to as the "Accreditation Act").

Procedo International Certification s. r. o.

Ulica Svornosti 42, 821 06 Bratislava - mestská časť Podunajské Biskupice
ID Number: 52 327 230

Organizational unit performing the activity of the Accredited Body:

Procedo International Certification s. r. o.

Workplace of the Accredited Body:

Ulica Svornosti 42, 821 06 Bratislava - mestská časť Podunajské Biskupice

Identification number of the Accredited Body: 672/Q-084

Area of accreditation: Management system certification

The certification body demonstrated its competence to perform the accredited activity fulfilling the accreditation requirements of **ISO/IEC 17021-1: 2015** Standard to carry out certification of Quality Management Systems for Medical Devices according to the **ISO 13485: 2016** Standard within the accreditation scope delineated in the Annex of this Certificate of Accreditation. The Annex shall form an integral part of the Certificate of Accreditation.


Number and date of issue of the accreditation decision: No. 672/11073/2023/1 dated 14.11.2023.

Validity of the accreditation decision:

The accreditation decision No. 672/11073/2023/1 dated 14.11.2023 is valid from 08.12.2023 to 09.11.2025.

The validity of this Accreditation Certificate expires upon the expiry of the accreditation decision, the decision on withdrawal of the accreditation pursuant to Section 31 or the expiry of the accreditation pursuant to Section 32 of the Accreditation Act.




Štefan Král
director

Scope of Accreditation

Accredited Body: Procedo International Certification s.r.o.
Ulica Svornosti 42, 821 06 Bratislava – mestská časť Podunajské Biskupice

Organizational unit performing the activity of the Accredited Body:
Procedo International Certification s.r.o.

Workplace of the Accredited Body:
Ulica Svornosti 42, 821 06 Bratislava – mestská časť Podunajské Biskupice

Identification number of the Accredited Body: 672/Q-084

№	Code	Main Technical Areas	Technical Areas
1	MD 1.1	1. Non-active Medical Devices	General non-active, non-implantable medical devices
2	MD 1.2		Non-active implants
3	MD 1.3		Devices for wound care
4	MD 1.4		Non-active dental devices and accessories
5	MD 1.5		Non-active medical devices other than specified above
6	MD 2.1	2. Active Medical Devices (Non-Implantable)	General active medical devices
7	MD 2.2		Devices for imaging
8	MD 2.3		Monitoring devices
9	MD 2.4		Devices for radiation therapy and thermo therapy
10	MD 2.5		Active (non-implantable) medical devices other than specified above
11	MD 4.1	4. In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/ Immunoematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
12	MD 4.2		In Vitro Diagnostic Instruments and software
13	MD 4.3		IVD medical devices other than specified above
14	MD 5.1		5. Sterilization Method for Medical Devices
15	MD 5.2	Moist heat	
16	MD 5.3	Aseptic processing	
17	MD 5.4	Radiation sterilization (e.g. gamma, x-ray, electron beam)	
18*	MD 5.8	Sterilization method other than specified above	
19	MD 6.1	6. Devices incorporating / utilizing specific substances / technologies	Medical devices incorporating medicinal substances
20	MD 6.2		Medical devices utilizing tissues of animal origin
21	MD 6.5		Medical devices utilizing nanomaterials
22	MD 6.6		Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
23	MD 7.1	7. Parts or services	Raw materials
24	MD 7.2		Components
25	MD 7.3		Subassemblies
26	MD 7.4		Calibration services
27	MD 7.5		Distribution services
28	MD 7.6		Maintenance services
29	MD 7.7		Transportation services
30	MD 7.8		Other services



Annex to the Certificate of Accreditation No. Q-084 dated 08.12.2023.

*The Annex is an integral part of the
Certificate of Accreditation*

* Note: This item does not include low temperature steam and formaldehyde sterilization, thermic sterilization with dry heat and sterilization with hydrogen peroxide (codes MD 5.5, MD 5.6 and MD 5.7 in Annex 6 of MSA-CS/01).

Workplaces of Certification Body, where certification activities are exercised (workplaces, where key activities are exercised, are marked with star):

№	Name and address of workplace
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