

# Certificate

Certificate No.: MD 1006099-1-1

Manufacturer: **77 Elektronika Műszeripari Kft.**

Fehérvári út 98.  
1116 Budapest  
Hungary

REPs Facility ID: F007987

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,  
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance  
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,  
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,  
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,

Scope: The design and development, manufacture, installation, servicing  
and distribution of urinalysis analyzers used in the diagnosis,  
management and detection.

The design and development, manufacture and distribution of urine  
biochemistry test strips and consumables for urine analyzers.

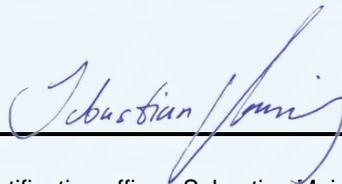
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 301559308-600

Issue Date: 2025-03-31

Effective Date: 2025-03-31

Expiry Date: 2028-03-30



Certification officer: Sebastian Mniszek  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>  
or calling 1-888-743-4652.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary  REPs Facility ID: F007987	Design and development, manufacture, distribution, installation and servicing
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary  REPs Facility ID: F007987	Manufacture and distribution

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