

Certificate

Certificate No.: MD 1006099-2-1

Manufacturer: **77 Elektronika Műszeripari Kft.**
Fehérvári út 98.
1116 Budapest
Hungary

REPs Facility ID: F008212

Certification criteria: ISO 13485:2016
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Contract manufacture of urinalysis analyzers used in the diagnosis, management and detection .
Contract manufacture of urine biochemistry test strips and consumables for urine analyzers.

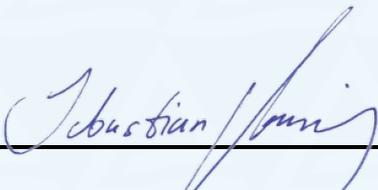
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Contract Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system 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: F008212	Contract manufacture
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary REPs Facility ID: F008212	Contract manufacture

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