

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1006099-1

Certificate Holder: 77 Elektronika Műszeripari Kft.  
Fehérvári út 98.  
1116 Budapest  
Hungary

Scope: Design and development, manufacture, distribution, installation and servicing of in vitro diagnostic urine analysers and related consumables, rapid test readers for healthcare professionals and near-patient testing used in field of clinical chemistry.

Design and development, manufacture, distribution and servicing of in vitro diagnostic blood glucose meters and ketone meters for self-testing used in diabetes monitoring.

Design and development, manufacture and distribution of in vitro diagnostic urine test strips and rapid test kits used in field of clinical chemistry for healthcare professionals and near-patient testing.

Design and development, manufacture and distribution of in vitro diagnostic blood glucose test strips and ketone test strips for self-testing used in diabetes monitoring.

Contract manufacture and servicing of in vitro diagnostic urine analysers and rapid test readers used in field of clinical chemistry.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 301567919-80

Effective date: 2025-11-18

Expiry date: 2028-11-17

Issue date: 2025-11-17

Replaces certificate SX 1006099-1 issued 2022-11-09



Marta Trzpil

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Distribution of continuous glucose monitoring system, sterile lancets, lancing devices and consumables for urine analysis.

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, manufacture, distribution, installation and servicing of in vitro diagnostic urine analysers and related consumables, rapid test readers for healthcare professionals and near-patient testing used in field of clinical chemistry.  Design and development, distribution and servicing of in vitro diagnostic blood glucose meters and ketone meters for self-testing used in diabetes monitoring.  Design and development, distribution of in vitro diagnostic blood glucose test strips and ketone test strips for self-testing used in diabetes monitoring.  Design and development, distribution of in vitro diagnostic urine test strips and rapid test kits used in field of used in field of clinical chemistry for healthcare professionals and near-patient testing.  Distribution of continuous glucose monitoring system, sterile lancets, lancing devices and consumables for urine analysis.
/02	77 Elektronika Műszeripari Kft. Sztregova utca 1. 1116 Budapest Hungary	Manufacture of in vitro diagnostic blood glucose meters and ketone meters for self-testing used in diabetes monitoring.  Manufacture of in vitro diagnostic blood glucose test strips and ketone test strips for self-testing used in diabetes monitoring.  Manufacture of in vitro diagnostic urine test strips and rapid test kits used in field of clinical chemistry for healthcare professionals and near-patient testing.  Contract manufacture and servicing of in vitro diagnostic urine analysers and rapid test readers used in field of clinical chemistry.

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