

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1006099-1

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

Scope: Design and development, production, distribution, installation and servicing of blood glucose measuring systems, urine analyzers and rapid test readers, including related consumables.

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.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

A handwritten signature in blue ink is written over a circular seal. The seal contains the TÜV Rheinland logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Zertifizierungsstelle'.

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, production, distribution, installation and servicing.
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary	Manufacture and warehouse of blood glucose measuring systems, urine analyzers, related consumables and parts. Manufacturing of SMT technology.

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