

# 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



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	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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A blue ink signature is written over a circular blue stamp. The stamp contains the TÜVRheinland logo and the text "TÜVRheinland LGA Products GmbH" and "Zertifizierungsstelle".

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