

# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization  
**77 Elektronika Műszeripari Kft.**  
**Fehérvári út 98.**  
**1116 Budapest**  
**Hungary**

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachments for scope and additional sites included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-11-18  
Certificate Registration No.: SX 60144357 0001  
An audit was performed. Report No.: 28250824 002  
This Certificate is valid until: 2022-11-17

Certification Body



Date 2019-11-18

*Maciej Sciera*  
Maciej Sciera



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60144357 0001  
**Report No.:** 28250824 002

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

**Scope:**

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

Additional sites included:  
77 Elektronika Műszeripari Kft.  
Sztregova utca 1  
1116 Budapest  
Hungary

Activity: Manufacture and warehouse of blood glucose measuring systems, urine analysers and the related consumables and parts. Manufacturing of SMT technology.

**Certification Body**



**Date: 2019-11-18**

*Maciej Sciera*  
**Maciej Sciera**

