

EC Certificate



Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1006099-1

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

Products: In-vitro Diagnostic Medical Devices for self-testing and for professional use:

- SensoCard blood glucose meter
- SensoCard Plus blood glucose meter
- SensoCard Test Strips
- CareSens control solutions

- SensoLite Nova blood glucose meter
- SensoLite Nova Plus blood glucose meter
- SensoLite Nova Test Strips
- CareSens control solutions

- GlucoTalk blood glucose meter
- GlucoTalk Test Strips
- GlucoTalk control solutions

Replaces EC Certificate Registration No. HL 60147430 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 93387425-40

Effective date: 2022-05-24

Expiry date: 2025-03-02

Issue date: 2022-05-24



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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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The scope of certification includes the following additional sites:

| No. | Location | Product groups manufactured |
|-----|---|--|
| /01 | 77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary | Activity: Design and development, distribution, installation and servicing of In-vitro diagnostic medical devices for self-testing and for professional use (blood glucose monitoring systems, urine analyzers). |
| /02 | 77 Elektronika Műszeripari Kft. Sztregova út 7. 1116 Budapest Hungary | Activity: Activities related to manufacture of IVDs. |
| /03 | 77 Elektronika Műszeripari Kft. Sztregova út 1. 1116 Budapest Hungary | Activity: Activities related to inspection, warehousing and final packaging of IVDs. |

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