EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapters I and III

Registration No.:	HX 1006099-1
Manufacturer:	77 Elektronika Kft. Fehérvári út 98. 1116 Budapest Hungary
EUDAMED Single Registration No.:	HU-MF-000004266
Products:	Products of class C for self-testing

CHEMISTRY/IMMUNOCHEMISTRY INSTRUMENTS

IVR 602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

W02010601 - DIABETES MONITORING

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.
If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.
If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.:	301559308-170
Effective date:	2026-02-12
Expiry date:	2031-02-11
Issue date:	2026-02-12

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

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EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapters I and III

Registration No.:	HX 1006099-1
Manufacturer:	77 Elektronika Kft. Fehérvári út 98. 1116 Budapest Hungary
EUDAMED Single Registration No.:	HU-MF-000004266
	CLINICAL CHEMISTRY
	IVR 602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
	W01010601 - BLOOD TEST STRIPS (CC) – RT & POC

Authorized representative(s): Not Applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-02-12

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Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1006099-1
Manufacturer:	77 Elektronika Kft. Fehérvári út 98. 1116 Budapest Hungary
EUDAMED Single Registration No.:	HU-MF-000004266
Classification:	Products of class C for self-testing
General product group name:	CHEMISTRY/IMMUNOCHEMISTRY INSTRUMENTS IVR 0602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease W02010601 - DIABETES MONITORING
Product name:	Dcont ETALON blood glucose meter Dcont ETALON B blood glucose meter Dcont NOVUM blood glucose meter Dcont ROLL blood glucose meter
Models and types:	D71-800100 D73-800200 D72-800300 D75-800100

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	301559308-330
Effective date:	2026-03-19
Expiry date:	2031-02-11
Issue date:	2025-03-19

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Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1006099-1
Manufacturer:	77 Elektronika Kft. Fehérvári út 98. 1116 Budapest Hungary
EUDAMED Single Registration No.:	HU-MF-000004266
Basic UDI-DI:	59973457DEK7V
Intended use:	Dcont® ETALON/NOVUM/ETALON B/ROLL blood glucose meter is an in vitro diagnostic medical device used for quantitatively measuring blood glucose in fresh capillary whole blood. The device is only used with ETALON Teszt test strip for self-testing. It is a nonautomated device intended to monitor glucose in diabetes mellitus.
Authorized representative(s):	Not Applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-02-12
1	Correction of device name	2026-03-19

EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1006099-2
Manufacturer:	77 Elektronika Kft. Fehérvári út 98. 1116 Budapest Hungary
EUDAMED Single Registration No.:	HU-MF-000004266
Classification:	Products of class C for self-testing
General product group name:	CLINICAL CHEMISTRY IVR 0602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease W01010601 - BLOOD TEST STRIPS (CC) – RT & POC
Product name:	ETALON Teszt test strip
Models and types:	ETN-9902
Basic UDI-DI:	59973457ETC8X

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	301559308-430
Effective date:	2026-03-19
Expiry date:	2031-02-11
Issue date:	2026-03-19

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
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This certificate can be validated on https://www.certipedia.com

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Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1006099-2
Manufacturer:	77 Elektronika Kft. Fehérvári út 98. 1116 Budapest Hungary
EUDAMED Single Registration No.:	HU-MF-000004266
Intended use:	The ETALON Teszt test strip with the dedicated blood glucose meter is intended to quantitatively measure glucose in fresh capillary whole blood. The test strip is an in vitro diagnostic medical device indicated for self-testing, and suitable for monitoring glucose in diabetes mellitus. The dedicated blood glucose meters are the Dcont® ETALON/NOVUM/ETALON B/ROLL blood glucose meters.
Authorized representative(s):	Not Applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-02-12
1	Editorial corrections	2026-03-19

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