Business Stream Products
Certification Department

TÜVRheinland®
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Date August 19, 2026

Notified Body Confirmation Letter
Reference. : 77ELE_PDQ0_HX_2025-04-11 replaced by
77ELE_PDQ0_HZ_2026-08-19

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

77 Elektronika Műszeripari Kft
Fehérvári út 98,
1116 Budapest
Hungary
SRN Number: HU-MF-000004266

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after May 26, 2022 and before July 9, 2024, without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by July 9, 2024 for the relevant devices.

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
    - 31 December 2027, for class D devices;
    - 31 December 2028, for class C devices;
    - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body

AUDIT_CERT_REVIEW
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Dcont ETALON blood glucose meter Basic UDI-DI: 59973457DEK7V	Class C, self-testing	Dcont ETALON, AutoSense, AutoSense Plus, blood glucose meters	7-029-400-2002 NB 1011
Dcont NOVUM blood glucose mete Basic UDI-DI: 59973457DEK7V	Class C, self-testing	SensoCard, blood glucose meters	HL 1006099-1 NB 0197
Dcont NOVUM blood glucose meter Basic UDI-DI: 59973457DEK7V	Class C, self-testing	N/A	7-029-400-2002 NB 1011
Dcont ETALON B blood glucose meter Basic UDI-DI: 59973457DEK7V	Class C, self-testing	SensoLite Nova, blood glucose meters	HL 1006099-1 NB 0197
Dcont ETALON B blood glucose meter Basic UDI-DI: 59973457DEK7V	Class C, self-testing	N/A	7-029-400-2002 NB 1011

Device name or Basic UDI-DI (under IVDR application)	**IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the IVDR device is a substitute device, identification of the corresponding IVDD device**	**IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification**
Dcont ROLL blood glucose meter Basic UDI-DI: 59973457DEK7V	Class C, self-testing	SensoCard Plus, SensoLite Nova Plus blood glucose meters	HL 1006099-1 NB 0197
Dcont ROLL blood glucose meter Basic UDI-DI: 59973457DEK7V	Class C, self-testing	Dcont MONDA, AutoSense Voice, blood glucose meters	7-029-400-2002 NB 1011
ETALON Teszt test strip Basic UDI-DI: 59973457ETC8X	Class C, self-testing	SensoCard, SensoLite Nova test strips	HL 1006099-1 NB 0197
ETALON Teszt test strip Basic UDI-DI: 59973457ETC8X	Class C, self-testing	ETALON Teszt, Ideál Teszt, AutoSense, test strips	7-029-400-2002 NB 1011
KETO Cont blood ketone meter Basic UDI-DI: 59973457KKD94	Class C, self-testing	N/A	7-031-306-2009 NB 1011
KETO Fit blood ketone meter Basic UDI-DI: 59973457KKD94	Class C, self-testing	N/A	7-031-306-2009 NB 1011
KETO Cont Teszt test strip Basic UDI-DI: 59973457KTC9V	Class C, self-testing	N/A	7-031-306-2009 NB 1011
KETO Cont Teszt test strip Basic UDI-DI: 59973457KTC9V	Class C, self-testing	N/A	7-031-306-2009 NB 1011
KETO Cont Teszt test strip Basic UDI-DI: 59973457KTC9V	Class C, self-testing	N/A	7-031-306-2009 NB 1011

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
UriSed mini Expert **Basic UDI-DI: 59973457UMBAQ**	B	UriSed mini urine microscopy analyzer	N/A - Device did not require a Notified Body certificate under Directive
sediMAX LITE Pro **Basic UDI-DI: 59973457UMBAQ**	B	sediMAX Lite urine microscopy analyzer	N/A - Device did not require a Notified Body certificate under Directive
Urilyzer Cell Pro **Basic UDI-DI: 59973457UMBAQ**	B	Urilyzer Cell urine microscopy analyzer	N/A - Device did not require a Notified Body certificate under Directive

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-04-23	77ELE_CL1860_2025-04-23	Initial issue
2026-08-19	77ELE_CL1860_2026-08-19	New devices have been added