

EC CERTIFICATE

Full Quality Assurance System

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

No. 7-029-400-2002

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

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

for the products / product categories:

Self-diagnosis systems for the measurement of blood sugar
(blood glucose meters and test strips)

applies a quality system which meets the requirements of Directive 98/79/EC on in vitro diagnostic medical devices, Annex IV.

Registry number of the related audit report: **NE/1006/2020**

This certificate is valid until **2025-02-12** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 3

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 13 February 2020.

Budapest, 2022-05-03


László Imre
Managing Director



EMKI 2832

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu



ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 7-029-400-2002

The certificate is valid for the following manufacturing sites / facilities:

77 Elektronika Műszeripari Kft.

H-1116 Budapest, Fehérvári út 98.

H-1116 Budapest, Sztregova utca 1.

The certificate is valid for the following products / models:

Self-diagnosis systems for the measurement of blood sugar (blood glucose meters and test strips)

dc61 AutoSense blood glucose meter

dc62 AutoSense Voice blood glucose meter

dc68 AutoSense Plus blood glucose meter

dc66 Dcont NEMERE blood glucose meter

dc67 Dcont MONDA blood glucose meter

dc71 Dcont ETALON blood glucose meter

dc72 Dcont NOVUM blood glucose meter

dc73 Dcont ETALON B blood glucose meter

ITB Ideál Teszt test strips

for Dcont Ideál, Dcont Ideál +, Dcont TREND, Dcont HUNOR, Dcont MAGOR,
Dcont NEMERE and Dcont MONDA blood glucose meters

AST AutoSense Test test strips

for AutoSense, AutoSense Voice and AutoSense Plus blood glucose meters

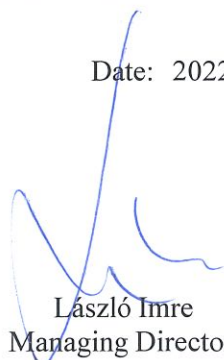
ETN ETALON Teszt test strips

for Dcont ETALON, Dcont NOVUM and Dcont ETALON B blood glucose meters

Issue: 3

Date: 2022-05-03

First issued: 2020-02-13


László Imre
Managing Director



EMKI

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