77 Elektronika Kft.
H-1116 Budapest, Fehérvári út 98. Tel.: +36 1 206 1480 Fax: +36 1 206 1481 www.e77.hu

EC DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer:

Manufacturer:	**77 Elektronika Műszeripari Kft.**
Address:	Fehérvári út 98., H-1116, Budapest, Hungary

herewith declares under sole responsibility that the medical device(s):

Product family:	**Urine test strips**	GMDN code:	30226
Product identification(s) and alternative make(s):	▪ LabStrip U11 Plus Urine Test Strip ▪ LabStrip U11 Plus GL Urine Test Strip		
Product category:	in vitro diagnostic medical device (for professional use)		
Product classification:	Non-listed product according to Annex II of the Directive 98/79/EC		

declared by the manufacturer as in vitro diagnostic medical devices in conformity with the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (furthermore: Directive 98/79/EC)

CONFORMS

with the essential requirements of Annex I and other applicable articles of the Directive 98/79/EC and possesses the performance intended by the manufacturer.

Conformity Assessment Procedure:	EC Directive 98/79/EC, Annex III. excluding Article 6.
Notified Body (if consulted):	N/A
Notified Body Identification Number (if consulted):	N/A
Type of Notified Body Certificate, Registration No. and Validity of Notified Body Certificate:	N/A
Quality Management System:	EN ISO 13485:2016
Certification Body:	TÜV Rheinland LGA Products GmbH
Certification No and Validity of Certification:	SX 60144357 0001 (2022.11.17.)

This is to attest that the aforementioned products do not endanger the health and safety of the patient, the operator or any other person if used properly.
I hereby declare that I maintain and update a quality management system whereby I monitor the experience acquired after the manufacture of the products and I take the necessary corrective actions.
I hereby declare that I immediately announce in accordance with Article 11 of the Directive 98/79/EC if any malfunction, deterioration of the features or performance of the product, or any deficiency or inadequacy of the user manual has caused or could have caused the death or severe deterioration of the state of health of the patient or the operator of the product.
I have compiled the technical documentation for aforementioned products in accordance with Article 3 of the Annex III of the Directive 98/79/EC that I shall hand over for supervision upon request by the Medical Device Department, Directorate of Control and Technology, National Institute of Pharmacy and Nutrition, up to at least 5 years from the date of manufacture of the last product. The technical documentation is available at manufacturer's headquarters.

Budapest, 18.11.2019

Oliver Babinszki
Quality and Environmental Management Director

77 Elektronika Műszeripari Kft.
1116 Budapest, Fehérvári út 98
Adószám: 10229064-2-44
BBRT: 10102093-01196703-00000005
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• Certified Management System
• DIN EN ISO 14001
• EN ISO 13485
• EN ISO 9001

CÉGJEGYZÉK SZÁMA: 01 09 061328 ALAPÍTVA: 1986 BBRT 10102093 - 01196703 - 00000005