



EU-DECLARATION OF CONFORMITY

Manufacturer name:	77 Elektronika Műszeripari Kft.
Address:	Fehérvári út 98., H-1116 Budapest
SRN number:	HU-MF-000004266

Product(s) name:	LabUReader Plus 2 semi-automated urine analyzer
Reference number:	UA3-9901-2
Basic UDI-DI:	59973457SAUALABCH
GMDN / EMDN	35918 / W02010701
Intended purpose of the device:	The LabUReader Plus 2 is a semi-automatic urine test strip analyzer and provides qualitative or semi-quantitative parameter concentration values in human urine. The analyzer evaluates dedicated LabStrip U11 Plus urine test strips for preliminary screening. The product is designed for professional use as an in vitro diagnostic medical device.
Classification:	A class

The manufacturer declares under its sole responsibility that the above-mentioned product complies with the requirements of the following legislation (s):

Applicable legislations:	Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices
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Notified Body name:	N/A
Notified Body address:	N/A
Notified Body Identification Number:	N/A
Conformity assessment procedure:	N/A
EC Certificate of conformity's type, number and validity:	N/A

Budapest, 23.08.2023.

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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