



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:	DocUReader 2 Pro urine analyzer
Reference number:	UD2-9902-1
Basic UDI-DI:	59973457SAUA4S
GMDN / EMDN	35918 / W02010701
Intended purpose of the device:	The DocUReader 2 Pro 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 system urine test strips for preliminary screening. The product is designed for professional use and may be used in a near-patient environment 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.


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Oliver Babinszki
Quality and Environmental Management Director

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