



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:	LabUMat 2 Automated Urine Chemistry Analyzer
Reference number:	UPA-9901-3
Basic UDI-DI:	59973457AUCA2A
GMDN / EMDN	35918 / W02010701
Intended purpose of the device:	LabUMat 2 is a fully automated urine chemistry analyzer. It is intended for professional in vitro diagnostic use in performing urinalysis testing, for in vitro qualitative or semi-quantitative determination of urine chemical parameters.
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, 25.05.2022.

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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