



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:	UriSed Cuvettes
Reference number:	URS-9961-1, URS-9971
Basic UDI-DI:	59973457CUV9W
GMDN / EMDN	61032 / W02010785
Intended purpose of the device:	UriSed Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyse uncentrifuged, human urine samples with UriSed sediment analysers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.
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

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