EU DECLARATION OF CONFORMITY

Manufacturer's Information

Manufacturer's Name:	**Norma Instruments Zrt.**
Manufacturer's SRN:	**HU-MF-000014244**
Manufacturer's Address:	**Papírgyár u. 58-59., 1038 Budapest, Hungary**

Product Information

Product Name:	**Norma Icon-5 Automated 5-part Hematology Analyzer with Autoloder**
Product Code:	**NI50H + NICA-AL50**
Basic UDI-DI:	**59991062Icon5A6 + 59991062AutoloaderGH**
Intended Purpose:	**Icon-5** is a 60 tests/hour laser scattering and impedance-based IVD hematology analyzer for laboratory use, using specific reagents, performing 5-part differential analysis of 27 hematology parameters of anti-coagulated human whole blood samples introduced in closed vials. The **Autoloader** is designed to further automate the operation of the analyzer by allowing the processing of up to 50 sample vials without operator interaction.
Risk Classification:	**Class A**
EMDN code:	Analyzer: W0202010101, Autoloader: W02060102

Applicable Regulations, Directives and Standards

Regulations:	2017/746/EU on *in vitro* diagnostic medical devices (IVDR)
Directives:	2011/65/EU on restriction of hazardous substances (ROHS) Classification: Category 8 Medical Device 2015/863/EU amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances 2014/30/EC on electromagnetic compatibility (EMC) 2014/35/EC on low voltage (LVD)
Standards:	EN 61010-1: 2010 (Third Edition) IEC 61010-2-101: 2015 (Second Edition) EN 60825-1: 2007 (Second Edition) EN 61326-2-6:2013

We, **Norma Instruments Zrt.**, as a manufacturer of the above-mentioned CE marked in-vitro medical devices, do hereby declare that this EU Declaration of Conformity is issued under our sole responsibility.

Devices covered by the present EU Declaration of Conformity is in conformity with **Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)** and other directives and standards specified above. This declaration is supported by the harmonized quality management system approval of **EN ISO 13485:2016** issued by **SGS Hungary Kft.** (HU15/7647). All supporting documentation is retained at the premise of the manufacturer.

Budapest, 2024/04/11

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Jakab Reisz
PRRC
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