

Manufacturer Declaration of Conformity

Manufacturer's name: Norma Instruments Zrt.
Place of business: 3530 Miskolc, Arany János u. 11-13. 2.em. 211. Hungary
Products: **Norma Icon-5 OP Automated 5-part Hematology Analyzer, Reagents and Control materials**
Classification: General/Other IVD
REF.- Number: Listed in the attachment below
Place of factory: Norma Instruments Zrt.
1038 Budapest, Papírgyár u. 58-59, Hungary

Instrument was tested according to:

EN 61010-1: 2010; (Third Edition);
IEC 61010-2-101: 2015;
EN 61326-2-6:2013 Standard;
EN 61000-4-3:2006+A1:2008+A2:2010 Standard;
EN 61000-4-6:2014 Standard;
EN 61000-4-4:2012 Standard;
EN 61000-4-5:2014 Standard;
EN 61000-4-11:2004 Standard;
EN 61000-4-2:2009 Standard;
EN 55011:2009+A1:2010 Standard;
EN 55022:2010 Standard;
EN 60825-1: 2007 (Second Edition).

We, **Norma Instruments Zrt.**, do herewith declare under our sole responsibility that the **CE marked** In Vitro Diagnostic Medical Devices listed in the attachment below

are in conformity with the Essential Requirements of **Annex I** and with the requirements listed in **Annex III** by the **Directive 98/79/EC** on *in vitro* diagnostic medical devices (*IVD Directive*)

and are in conformity with the requirements of the harmonized quality management system of EN ISO 13485.

Budapest, 2019/01/30

NORMA INSTRUMENTS Zrt.
3530 Miskolc,
Arany J. utca 11-13 2/211
Adószám: 24742159-2-05



.....
Gergely Domonkos Horváth
Chief Executive Officer
Norma Instruments Zrt.

A handwritten signature in blue ink, located in the bottom right corner of the page.

Attachment

Product Names	Product Codes	Volume
Icon-5 OP Hematology Analyzer	NO50H	
Norma-iDil5 OP	IC-11775	5 L
Norma-iDil5 OP	IC-11771	10 L
Norma-iLyse5 OP	IC-21771	1 L
Norma-iClean5 OP	IC-51771	1 L
Norma-iClean5 OP	IC-51775	5 L
Norma-iRP51 OP	IC-91771	100 tests
Norma-iRP52 OP	IC-91772	250 tests
NormaCont5+ low 3ml	NIC-0P53L	3 mL
NormaCont5+ normal 3ml	NIC-0P53N	3 mL
NormaCont5+ high 3ml	NIC-0P53H	3 mL
NormaCont5+ KIT KL (6L)	NIC-053KL	6 x 3 ml (6L)
NormaCont5+ KIT KN (6N)	NIC-053KN	6 x 3 ml (6N)
NormaCont5+ KIT KH (6H)	NIC-053KH	6 x 3 ml (6H)
NormaCont5+ KIT K1 (2L,2N,2H)	NIC-053K1	6 x 3 ml (2L,2N,2H)