

The management system of

NORMA Instruments Zrt.

H - 3530 Miskolc, Arany János u. 11-13.

H - 1038 Budapest, Papírgyár u. 58-59.



has been assessed and certified as meeting the requirements of

MSZ EN ISO 13485:2016

For the following activities

Development, production and distribution of blood analysis systems for the in-vitro diagnostic (IVD) market.

Further clarifications regarding the scope of this certificate and the applicability of MSZ EN ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid from 9 July 2018 until 28 April 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 17 April 2021

Issue 2. Certified since 28 April 2015

Date of approval: 9 July 2018

Authorised by

Tohl András

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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 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).

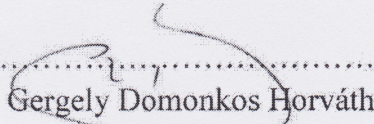
We, **Norma Instruments Zrt.**, do herewith declare under our sole responsibility that the **CE marked** In Vitro Diagnostic Medical Devices listed in the attachment below

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

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Gergely Domonkos Horváth
Chief Executive Officer
Norma Instruments Zrt.

CE



Attachment

Product Names	Product Codes	Volume
Icon-5 Hematology Analyzer	NI50H	
Norma-iDil5 5l	IC-11755	5 L
Norma-iDil5 10l	IC-11751	10 L
Norma-iLyse5 1l	IC-21751	1 L
Norma-iClean5 1l	IC-51751	1 L
Norma-iClean5 0,5l	IC-51755	0.5 L
Norma iRP51 (100t)	IC-91751	100 tests
Norma iRP54 (400t)	IC-91754	400 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)

