

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-3 Automated 3-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 61010-1:2001 (Second Edition);
EN 61010-1:2010;
EN 6101-2-101:2002;
EN 61326-1:2003;
EN 61326-2-6:2013;
EN 55011:2009 A1:2010;
EN 61000-3-2:20006 +A1:2009+ A2:2009;
EN 61000-3-3:2008

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

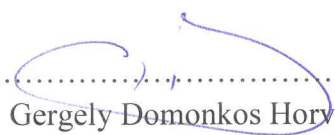
are in conformity with the Essential Requirements of **Annex I** and with the requirements listed in **Annex III** by the **Directive 98/79/EC** on *in vitro* diagnostic medical devices (*IVD Directive*)

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.



Attachment:

Product Names	Product Codes	Volume
Icon-3 Hematology Analyzer	NI30H	
Norma-iDil3	IC-11735	5 L
Norma-iDil3	IC-11731	10 L
Norma-iDil3	IC-11732	20 L
Norma-iLyse3	IC-21731	1 L
Norma-iSol3	IC-41731	1 L
Norma-iSol3	IC-41735	5 L
Norma-iHClean	IC-81731	100 ml
Norma-iHClean	IC-81730	1 L
Norma-iHClean 4ml	IC-81734	4 ml
Norma-iRP31	IC-91711	100 tests
Norma-iRP35	IC-91715	500 tests
NormaCont3+	NIC-0P32L	2,5 ml
NormaCont3+	NIC-0P32N	2,5 ml
NormaCont3+	NIC-0P32H	2,5 ml
NormaCont3+ KIT K1	NIC-032K1	6 x 2,5 ml (2L,2N,2H)
NormaCont3+ KIT K2	NIC-032K2	8 x 2,5 ml (1L,6N,1H)
NormaCont3+ KIT K3	NIC-032K3	10 x 2,5 ml (2L,6N,2H)
NormaCont3+ KIT K4	NIC-032K4	12 x 2,5 ml (2L,8N,2H)
NormaCont3+ KIT KL	NIC-032KL	6 x 2,5 ml (6L)
NormaCont3+ KIT KN	NIC-032KN	6 x 2,5 ml (6N)
NormaCont3+ KIT KH	NIC-032KH	6 x 2,5 ml (6H)
NormaCal3	NIC-CAL32	2,5 ml