

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 Names	Product Codes	Basic UDI-DI	Intended Purpose
Norma-iDiI3	IC-11735	59991062iDiI3CH	Norma reagents and reagent packs are intended to be used with Norma's automated hematology analyzers. The diluent reagent is a buffered, stabilized, and micro-filtered electrolyte solution for automated dilution of blood samples, quantitative determination of red blood cells (RBC), quantitative and qualitative determination of white blood cells (WBC), 3- or 5-part WBC subpopulations, platelets (PLT) and for 3-part analyzers also measurement of hemoglobin (HGB) concentration. The lyse reagent is a stabilized and micro-filtered lysing agent for stromatolysis of red blood cells (RBC), for quantitative determination of white blood cells (WBC), for WBC 3-part (lymphocytes [LYM], mid-size cells [MID], granulocytes [GRA]) or 5-part ((lymphocytes [LYM], monocytes [MON], neutrophils [NEU], eosinophils [EOS], basophils [BAS]) differentiation and hemoglobin (HGB) concentration measurement of human blood. iSol3 and cleaner reagents are buffered, stabilized, and micro-filtered electrolyte solutions used for conditioning and cleaning of specific tubing sections and chambers. The reagents and reagent packs are intended for laboratory professional use as an <i>in vitro</i> diagnostic medical device.
Norma-iLyse3	IC-21731	59991062iLyse3SF	
Norma-iSol3	IC-41731	59991062iSol3GQ	
Norma-iSol3	IC-41735		
Norma-iDiI5	IC-11755	59991062iDiI5CM	
Norma-iLyse5	IC-21751	59991062iLyse5SK	
Norma-iClean5	IC-51755	59991062iClean53E	
Norma-iRP20	IC-91720	59991062iRP26M	
Norma-iRP21	IC-91721		
Norma-iRP31	IC-91711	59991062iRP36P	
Norma-iRP35	IC-91715		
Norma-iRP51	IC-91751	59991062iRP56T	
Norma-iRP54	IC-91754		
Norma-iRP51 OP	IC-91771	59991062iRP50PC2	
Norma-iRP52 OP	IC-91772		
Norma-iHClean	IC-81731	59991062iHCleanV4	iHClean is a stabilized and micro-filtered hypochlorite solution for intensive oxidative rinsing and cleaning of capillaries, tubing, and chambers of Norma hematology analyzers: Icon-3, i3LAB, Icon-5 and Icon-5 OP.

Classification, EMDN

Risk Classification:	Class A
EMDN Code:	W0103010105

Applicable Regulations, Directives and Standards

Regulations:	2017/746/EU on <i>in vitro</i> diagnostic medical devices (IVDR)
Directives:	1907/2006/EC on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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 are 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.

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