NeoMedica
bioscience technology

EC Declaration of Conformity

According to Annex III of
In Vitro Diagnostic Medical Devices Directive 98/79/EC

NeoMedica d.o.o.
Bul. Sv. Cara Konstantina 82-86, 18000 Nis
Republic of Serbia, Europe

We declare in our own responsibility that conformity of the products listed below is according to the essential requirements of Annex I of the In Vitro Diagnostic Medical Devices Directive 98/79/EC.
The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III, Directive 98/79/EC, except of Point 6.

Product: Automated Hematology Analyzers: Phoenix NCC-51 with autoloader and Phoenix NCC-61 and reagents for Automated Hematology Analyzer; designed for NeoMedica Phoenix NCC-51 with autoloader and Phoenix NCC-61

Product name	Ref. No.	EDMA code
Phoenix NCC-51 with autoloader	N117929	23.01.10.01
Phoenix NCC-61	N117961	23.01.10.01
Neo Diluent E	N117505	13.01.01.01
Neo Lyse E	N117502	13.01.01.01
Neo Sheath E	N117524, N117525	13.01.01.01
Neo Cleaner E	N117535, N117534	13.01.01.01
Neo Rinse E	N117500	13.01.01.01

Classification: Other IVDD (Non Annex II, Non Self testing, For professional use, Self-Declaration)

EDMA Classification: 23.01.10.01 Analyzer, laboratory, hematology, cell counting, automated
13.01.01.01 CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheath fluids)

Applicable Standards: EN ISO 9001:2015
EN ISO 13485:2016
EN ISO 15223-1:2016
EN 61326-1:2013

Certification body: World Registrar Group Europe

World Registrar Group

AIA-BAR ACCREDITED

Certificates: SRPS ISO 9001:2015
ISO 13485:2016

EC Representative:
We hereby explicitly appoint Wellkang Ltd. located at The Black Church, St. Mary's Place, Dublin 7, D07P4AX, Ireland & Unit 5, Rathcross Business Park, Ashbourne, Co. Meath, A84RD28, Ireland to act as our European Authorised Representative as defined in the EU Directive 98/79/EC.

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Signed by:	.....
Name:	Saša Jokić
Position:	CEO
Place:	NeoMedica d.o.o., Nis, Serbia, Europe
Date:	April 2020