NeoMedica
bioscience technology

EC Declaration of Conformity

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

NEOMEDICA DOO NIŠ
Bulevar Svetog 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 immunology analyzer NAISSA IMMUNOANALYZER and consumables for automated immunology analyzer designed for NAISSA

Product name	Ref. No.	EDMA code
NAISSA IMMUNOANALYZER	N100YV3	21.02.10.01
NAISSA WASH A	N1901NA	21.02.10.01
NAISSA WASH B	N1902NB	21.02.10.01
NAISSA SANITIZING SOLUTION	N1904NS	21.02.10.01
NAISSA System liquid	N1905NL	21.02.10.01

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

EDMA Classification: 21.02.10.01 IC&II Hardware + accessories + consumables + software

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.07.11 11:42:52 EEST
Reason: MoldSign Signature
Location: Moldova

Certification body: United registrar of systems

Certificates: SRPS ISO 9001:2015
ISO 13485:2016

EC Representative:
We hereby explicitly appoint Wellkang Ltd. located at The Enterprise Hub, Nw Business Complex, 1 Beraghmore Road, Derry, Northern Ireland, BT48 8SE to act as our European Authorised Representative as defined in the EU Directive 98/79/EC.

CE

Signed by: .....

Name: Saša Tričković

Position: CEO

Place: NEOMEDICA DOO NIŠ, Republic of Serbia, Europe

Date: March 5, 2022

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