Digitally signed by Botnaru Andrei
Date: 2023.10.26 13:47:58 EEST
Reason: MoldSign Signature
Location: Moldova

EU Declaration of Conformity

Manufacturer:	Infitek Co., Ltd. Add: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan, Shandong, China.
European Representative:	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain
SRN:	ES-AR-000001202
Product Name:	Auto Hematology Analyzer
GMDN Code:	35476
Basic UDI-DI:	697548844HEMA22S2

Intended Use: The analyzer is intended for screening in the clinical examination.

Classification (IVDR, Annex VIII): Class A, Rule 5.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Applied standards, common specification, guidance:
ISO 14971:2019, IEC 61010-1:2010+A1:2016, IEC 61010-2-101:2018, IEC 61326-1:2020, IEC 61326-2-6:2020, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612: 2002/AC:2002, EN 62366:2015+AC:2015, EN 62304:2006+A1:2015, EN ISO 15223-1:2021.

Signature:

INFITEK CO., LTD Infitek

Name:
Position: General Manager

Place/date: China, Jul.15th, 2023

CE

File No.: CE/23-02, ver.A/0