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:	Biochemistry Analyzer
GMDN Code:	56667
Basic UDI-DI:	697548844BA22MW

Intended Use: The instrument is auto chemistry analyzer for in vitro diagnostic use in clinical laboratories and designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebrospinal fluid samples.

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:

Name:
Position: General Manager

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

INFITEK CO., LTD.

Digitally signed by Botnaru Andrei
Date: 2023.10.26 13:44:26 EEST
Reason: MoldSign Signature
Location: Moldova

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