

EU Declaration of Conformity

Manufacturer: CARETIUM MEDICAL INSTRUMENTS CO., LTD
7th Floor Building 1, Beishan Industrial Park, Beishan Road,
Yantian, Shenzhen, Guangdong 518000 China

SRN: CN-MF-000016852

European Representative: Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

SRN: ES-AR-000001202

Product Name: XI-921 Series, XI-931 Series, XI-1021 Series and Reagents for
Models: Electrolyte analyzer

Basic UDI-DI: 697149851010003F

Intended Use: Used for the measurement of the content of K⁺, Na⁺, Cl⁻, Li⁺, pH, Ca²⁺(concentration), HCO₃⁻ in human serum, plasma or urine.

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.

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 ISO 23640:2015, EN 62366:2015+AC:2015, EN 62304:2006+A1:2015, EN ISO 15223-1:2021.

Signature:



Name:

Position:

General Manager

Place/date:

China, May. 15th, 2024

