CE Declaration of Conformity

Manufacture: Caretium Medical Instruments CO., Ltd
Beishan Industrial Park 7 th Floor Building 1, Beishan Road, Yantian, Shenzhen 518083 China

EC-Representative: Prolinx GmbH
Brehmstr.56 40239 Dusseldorf Germany

Product: Electrolyte Analyzer

Model: XI-931(XI-931A,XI-931B,XI-931C,XI-931D,XI-931E,XI-931F， XI-931AT,XI-931BT,XI-931CT,XI-931DT,XI-931ET,XI-931FT)

Product: Reagent for Electrolyte Analyzer

Model: XI-931(XI-931A,XI-931B,XI-931C,XI-931D,XI-931E,XI-931F， XI-931AT,XI-931BT,XI-931CT,XI-931DT,XI-931ET,XI-931FT)

Classification: Others

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above-mentioned products meet the provisions of the DIRECTIVE 98/79/EC on in vitro Diagnostic Medical Devices. All supporting documentations are the under the premises of the manufacturer.

Standards Applied:
List of (harmonized) standards for which documented evidence for compliance can be provided as attachment

Place , Date of Issue: Shenzhen, 2017-05-01
Signature:
Name of Authorized Signatory: Mr. Li Shoufu
Position Held in Company: Management Representative

Digitally signed by Varman Irina
Date: 2021.07.08 16:00:34 EEST
Reason: MoldSign Signature
Location: Moldova