

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-921(XI-921A,XI-921B,XI-921C,XI-921D,XI-921E,XI-921F)

Product: Reagent for Electrolyte Analyzer

Model: XI-921(XI-921A,XI-921B,XI-921C,XI-921D,XI-921E,XI-921F)

Classification: Others

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above-mentioned products meet the provisions of the DIRECTIVE 93/42/EEC 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

