

Declaration of Conformity

Manufacturer:

Meizhou Cornley Hi-Tech Co.,Ltd.

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European Representative:

Caretechion GmbH

Niederrheinstr. 71, 40474 Duesseldorf, Germany

Product Name:

Blood Gas & Electrolyte Analyzer

Model:

See Attached List

Classification:

Others

Conformity Assessment Route:

IVDD 98/79/EC Annex III (excludes section 6)

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

General Applicable Directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223-1:2016 EN ISO 18113-1:2011

EN 61010-1:2010 EN ISO 13612:2002 EN ISO 18113-2:2009 EN 62304:2006

EN 61326-1:2013 EN 61326-2-6:2013 EN 61010-2-101:2017 EN 62366:2008

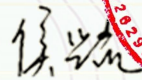
Place and Date of Issue:

Shenzhen, April, 21st 2020

Position held in company:

General Manager

Signature:



List of products:

Product	Type
Instrument:	
Electrolyte Analyzer	AFT-800A, AFT-800B, AFT-800D, AFT-800E, AFT-800F, AFT-800G, AFT-800H
Reagent and Accessories:	
Calibration Standard Solution	
Electrolyte Quality Control (H/M/L)	R1: Level 1 R2: Level 2 R3: Level 3
Electrolyte Quality Control (M)	R2: Level 2
Refill Solution for K+, Na+, Cl-, Ca ⁺⁺ , pH electrode	
Refill Solution for Reference electrode	
Refill Solution for Li ⁺ electrode	
Multi-enzyme De-proteinizer	
Conditioning Solution	
Cleaning Solution	
Reference Electrode	
Potassium (K ⁺) Electrode	
Sodium (Na ⁺) Electrode	
Chloride (Cl ⁻) Electrode	
Calcium (Ca ⁺⁺) Electrode	
Lithium (Li ⁺) Electrode	
pH Electrode	
