CORNLEY **Meizhou Cornley Hi-Tech Co.,Ltd.**

Add: Nanshan Industrial Estate, Baigong, Meixian, Guangdong Province, P. R. China

Tel : 86-753-2878808 Fax : 86-753-2878811 Website : www.cornley.com

EC DECLARATION OF CONFORMITY

MANUFACTURER: *MEIZHOU CORNLEY HI-TECH CO.,LTD NANSHAN INDUSTRIAL ESTATE, BAIGONG, MEIXIAN, GUANGDONG PROVINCE, P.R.CHINA-514765*

EC REP

EUROPEAN REPRESENTATIVE: *RENAULT PETERSEN LIMITED. BASED IN COUCHING HOUSE, COUCHING STREET, WATLINGTON, OXFORDSHIRE OX49 5PX*

PRODUCT: *ELECTROLYTE ANALYZER, MODEL: SEE ATTACHED LIST*

CLASSIFICATION*(ACCORDING TO ANNEX II)*: OTHERS

CONFORMITY ASSESSMENT ROUTE: *ANNEX III*

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.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONIZED) STANDARDS*

NOTIFIED BODY:

IDENTIFICATION NUMBER:

(EC) CERTIFICATE(S):

START OF CE-MARKING: *2017-07-01 (DATE), ET1608001 (LOT NO.)*

PLACE, DATE OF ISSUE: *SHENZHEN, CHINA 2017-07-08*

SIGNATURE:

NAME: HAU WANCHON

POSITION: GENERAL MANAGER

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LIST OF PRODUCTS:

PRODUCT	TYPE
Instrument:	
Electrolyte Analyzer	*AFT-800A, AFT-800B, AFT-800D, AFT-800E, AFT-800F, AFT-800G, AFT-800H, AFT-800A /AU, AFT-800B /AU, AFT-800D /AU, AFT-800E /AU, AFT-800F /AU, AFT-800G /AU, AFT-800H/AU*
Reagent and Accessories	
Calibration Standard Solution	
Electrolyte Quality Control	R1: Level 1 R2: Level 2 R3: Level 3
TCO2 Quality Control	R1:Level 1 R2:Level 2
Refill Solution for K^+, Na^+, Cl^-, Ca^{++}, pH electrode	
Refill Solution for Reference electrode	
De-proteinizer	
Conditioning Solution	
Cleaning Solution	
TCO2 Reagent(TCO2 Reaction Solution)	
Reference Electrode	
Potassium (K^+) Electrode	
Sodium (Na^+) Electrode	
Chloride (Cl^-) Electrode	
Calcium (Ca^{++}) Electrode	
Lithium (Li^+) Electrode	
pH Electrode	

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7--LIST OF *(HARMONIZED) STANDARDS*:

DOCUMENT NUMBER	TITLE OF DOCUMENT
EN 980:2008	Symbols for use in the labelling of medical devices
EN ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2009	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005
EN 62304:2006	Medical device software - Software life-cycle processes IEC 62304:2006
EN 62366:2008	Medical devices - Application of usability engineering to medical devices IEC 62366:2007