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EC Declaration of Conformity
(Directive 98/79/EC)

Manufacturer:
Chengdu Polytech Biological Technology Co.,Ltd
Address:
No.1 Tianhe Road,Western Zone of Chengdu High and New Tech, Sichuan, China.

European Representative:
Renault-Petersen Limited
Address:
5 Bankside, Hanborough Business Park, Witney OX29 8LJ UK

Product Details: SMT100 Chemistry Reagent

Classification: Other/General
Conformity
Assessment Route: Annex III without section 6

We herewith declare that above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro medical devices. All supporting documentation is retained under these premises and/or the premises of manufacturer's subcontractors.

DIRECTIVE

General applicable directives:
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices (IVDD 98/79/EC)

Standard Applied:
Standards list for which documented evidence of compliance can be provided as attachment.

Quality assurance system standards: EN ISO 13485: 2012; EN ISO 13485: 2012/AC: 2012(Certification number: SX 60079107 0001)

Place, Date of Issue: Chengdu, China, February 08, 2017
Signature:
Name/Position: Peng Ran/ Managing Director

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Applied Standard List

Standard	Title
EN ISO 13485:2012 EN ISO 13485:2012/AC:2012	Medical devices-Quality management systems-Requirements for regulatory purposes
EN ISO 14971:2013-04	Medical devices-Application of risk management to medical devices
EN ISO 15223-1:2016-11	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements
EN ISO 18113-1:2013-01	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2013-01	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 2: In vitro diagnostic reagents for professional use
EN 13612:2002-08	Performance evaluation of in vitro diagnostic medical devices
EN 13640:2002	Stability testing of in vitro diagnostic reagents
EN 62366:2016-05; VDE 0750-241:2016-05	Medical devices-Application of usability engineering to medical devices

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SMT-100 Chemistry Reagent types list:

The Types of Biochemistry Reagent Disc	
14Conventional Parameters	TC,ALT,AMY,ALB,ALP,GLU,GGT,UA,AST,TBIL,UREA,CREA ,TG,TP
13 Health Check Parameters	ALT,ALB, AST, AMY, CA, CREA, GLU, TBIL, CK,TG,UREA, PHOS, TP, GLOB*
10 liver Function	ALT,TBA,AMY,ALB,ALP.GGT,AST,TBIL,CHE,TP
8 Kidney Function	Co2, CA,ALB,GLU,UA,P,UREA,CREA
7 Electrolyte	K+, Na+, Cl, CA, CO2, Mg, P
6 Lipid Parameters	TC,ALT,DHL,LDL*,GLU,AST,TG