Declaration of Conformity

according to the In vitro diagnostic Medical Devices Directive 98/79/EC

Manufacturer: Changsha Sinocare Inc.

Address: No.265 Guyuan Road, Hi-tech Zone, Changsha, Hunan Province, 410205, People's Republic of China.

We declare under our sole responsibility that

the Medical Device

Product Name	:	Blood Glucose monitoring system
Type/model, batch/serial number, possibly sources and number of items (Where applicable)	:	Safe AQ Angel Blood Glucose Meter Safe AQ Angel Blood Glucose Strip Blood Glucose Control Solution
of class according to directive 98/79/EC	:	The product classification is ListB.

meets all the provisions of the directive 98/79/EC which apply to it.

Applied harmonised standards, national standards or other normative documents

EN ISO 15197:2015
In vitro diagnostic test systems requirements for blood-Glucose monitoring systems for Self-testing in managing diabetes mellitus(ISO 15197:2013)

EN ISO14971:2012
Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

EN23640:2013
In vitro diagnostic medical devices-evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

IEC 61010-1: 2010
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

IEC 61326-1: 2012
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

IEC 61010-2-101: 2015
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC-61326-2-6: 2012
Electrical requirements for measurement, control and laboratory use –EMC requirements- Part 2-6: Particular requirements –In vitro diagnostic (IVD) medical equipment

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)

Digitally signed by Jighili Tatiana
Date: 2020.12.25 15:06:54 EET
Reason: MoldSign Signature
Location: Moldova

	EN ISO 18113-4:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4：In vitro diagnostic reagents for self-testing (ISO18113-4:2009) **IEC 62366:2007(First Edition)+A1:2014** Medical devices-Application of usability engineering to medical devices	**EN ISO 18113-5：2011** In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009) **IEC 62304：:2015** Medical device software-Software life cycle processes
Conformity assessment procedure	Council directive 98/79 /ECAnnex IV except setion 4、6	
Notified Body (if consulted)	TÜV SÜD Product Service GmbH Ridlerstraβe 65 · 80339 München Germany NB ID 0123	
EC-Representative	Shanghai International Holding Corp.GmbH(Europe) Eiffestraβe 80,20537 Hamburg,Germany	
No.265 Guyuan Road, Hi-tech Zone,Changsha, Hunan Province, 410205, People's Republic of China	Li Shaobo General Manager	
2/28/2017 (place and date)	Li Shaobo. (name and signature, function)	

SINOCARE INC. 长沙三诺生物传感股份有限公司 CHANGSHA