Sinocare 三诺 CHANGSHA SINOCARE INC.

Digitally signed by Bolea Petru
Date: 2021.03.17 08:31:19 EET
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

Manufacturer	Authorized European Community Representative
Changsha Sinocare Inc. No.265 Guyuan Road, Hi-tech Zone, Changsha, Hunan Province, 410205, People's Republic of China.	Shanghai International Holding Corp. GmbH (Europe) Eiffestraβe 80,20537 Hamburg, Germany

Declaration:	We hereby declare under our sole responsibility that the following products meet the provisions of the Council Directive 98/79/EC for *in-vitro* diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of Changsha Sinocare Inc.
Classification:	IVDD List B
Product Group:	Self-testing devices for the measurement of blood glucose
Product Name:	Blood Glucose Monitoring System
Type/Model:	Safe-Accu Blood Glucose Meter Safe-Accu Blood Glucose Test Strip Blood Glucose Control Solution
Directive(s):	Council Directive 98/79/EC concerning in vitro diagnostic medical devices
Applied standards	ISO 13485:2016&EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
	ISO15197:2013&EN ISO15197:2015 In vitro diagnostic test systems-Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus
	ISO 14971:2019 & EN ISO14971:2019 Medical devices - Application of risk management to medical devices
	ISO/TR24971:2020 & CEN ISO/TR24971:2020 Medical Devices -Guidance on the application of ISO14971
	ISO 18113-1:2009&EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
	ISO 18113-2:2009&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 18113-3:2009& EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instrument for professional use
	ISO 18113-4:2009& 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	
	ISO 18113-5:2009& EN ISO 18113-5:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instrument for self-testing	
	ISO 15223-1:2016&EN ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements.	
	IEC 62366-1:2015& EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices	
	ISO 23640-2011& EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents	
	IEC 61010-1: 2010 +A1:2016 & EN 61010-1: 2010/FprA1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	
	IEC 61010-2-101: 2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
	IEC 61326-1: 2012& EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	
	IEC 61326-2-6: 2012& EN 61326-2-6:2013 Electrical requirements for measurement, control and laboratory use – EMC requirements- Part 2-6: Particular requirements –In vitro diagnostic (IVD) medical equipment	
	IEC 62304:2006/AMD1:2015& EN 62304:2006/A1:2015 Medical device software-software life cycle processes	
Certifications:	**Certificate No**	**Valid Until**
EC Certificate	V1 060250 0017 Rev.01	2022-02-26
Notified Body:	**Notified Body:**	**Notified Body No:**
	TÜV SÜD Product Service GmbH Ridlerstraβe 65 80339 München Germany	0123
Conformity assessment procedure	Council directive 98/79 /EC Annex IV except section 4.6	
Changsha Sinocare, Inc. Responsible Authority	**Signature:** Zhou Qian	**Date:** 12/10/2020
	Zhou Qian, Director, Regulatory Affairs Dept.	