



EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC



Manufacturer: Jiangsu Yuyue Medical Instruments Co., Ltd

Address: No 36 West Yandu Road, Yandu New District, Yancheng Jiangsu 224005, P.R.China

EC Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

We declare under our sole responsibility that

the medical device(s)	Product Name	:	Mercury free clinical thermometer
	Type/model, identification of product allowing traceability (Where applicable)	:	CRW-1108
of class	according to annex IX of directive 93/42/EEC	:	Im

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	EN ISO 13485:2003+AC:2009	EN ISO 9001:2008
	EN ISO 12470-1:2000+A1:2009	EN 1041:2008
	EN 980:2008	EN ISO 10993-1:2009
	EN ISO 10993-5:2009	EN ISO 10993-10:2009
	EN ISO 14971: 2009	

Conformity assessment procedure

MDD 93/42/EEC Annex V

Notified Body (name & number)

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH Pilatuspool 2-20355 Hamburg Germany, CE0482

Certificate & number

Certificate No.: 7369GB416200221

Signed this Day/ 21 of Month/ Feb of Year/ 2020, Place YANCHENG, Country (CHINA)

Signature (on behalf of the manufacturer)

Typed name: XU XUE HAI

Position/Title: GENERAL MANAGER

Stamp/Seal:

