

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Xuzhou Yongkang Electronic Science Technology Co., Ltd. 2nd&3rd floor of Building No.5, Block B, Huaihai Biomedical Industry Park, No. 5 Tengzhai North Road, Xuzhou High-tech Industrial Development Zone, 221000 Xuzhou, PEOPLE'S REPUBLIC OF CHINA
SRN of manufacturer:	CN-MF-000018890
Name and address of the EU Authorized Representative:/	Prolinx GmbH Brehmstr. 56, 40239 Düsseldorf Germany
SRN of EU Authorized Representative	DE-AR-000005129

We declare under our sole responsibility that:

Name of the medical device: /	Infrared Thermometer
Trade name:/	YONKER
Product Model:/	YK-IRT2,YK-IRT4
EMDN code:/	V0301010202 NON-CONTACT DIGITAL THERMOMETERS
Intended purpose:/	The infrared thermometer of we produced is specially for measuring body temperature, it can measure human forehead temperature, it suitable for medical unit and home use.
Basic UDI-DI:/ of class: /	69217452IRTFUJ Class IIa, Rule10 according to annex VIII of Regulation (EU) 2017/745
Conformity assessment: /	Annex IX excluding chapter II according to Para.1 of Article 52(6) of Regulation (EU) 2017/745
Applicable standards:/	EN ISO 13485: 2016/A11:2021 EN ISO 14971: 2019 /A11:2021 EN ISO 20417:2021 ISO 15223-1:2021+Amd 1:2025 EN ISO 10993-1:2025 EN ISO 10993-5: 2009 EN ISO 10993-10:2023 EN ISO 10993-23: 2021 IEC 60601-1:2005/AMD1:2012/AMD2:2020 IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-11:2015/AMD1:2020 EN ISO 80601-2-56:2017+A1:2020 IEC 60601-1-6:2010+A1:2013+A2:2020 EN 62366-1:2015+A1:2020 EN 62304:2006+A1:2015 EN ISO14155:2020

Other applicable Regulations & RoHS 2011/65/EU
Directives:/ REACH (EC) No 1907/2006
CS reference: / NONE

Notified Body: /

TÜV SÜD Product Service GmbH

Address:Ridlerstraße 65, 80339 Munich,Germany

Notified Body Number:/

0123

Certificate No.: /

G10 128715 0002 REV.00

Issue date of the Certificate:/

2026-06-10

Expire date of the Certificate:/

2029-09-18

Xuzhou,2026.06.11

Ort, Datum / Place, date /

Lieu, date / Luogo, data

Zhao Xuecheng, General Manager

Name und Funktion / Name and function /

Nom et fonction / Nome e funzione

