Cofoe Medical Technology Co., Ltd.	File name	Declaration of conformity
	File No.	KF-JS-TCF-N1917-11
	Version	A2

Cofoe Medical Technology Co., Ltd.
816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Infrared Thermometer

MODEL CODE: KF-HW-001, KF-HW-002, KF-HW-003, KF-HW-004, KF-HW-005

CLASSIFICATION - *ANNEX IX*: Class IIa, rule10

CONFORMITY ASSESSMENT ROUTE: ANNEX II, EXCLUDING SECTION 4

UMDNS CODE: 14036 Thermometers, Infrared

We [Cofoe Medical Technology Co., Ltd. Located in 816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan, PEOPLE'S REPUBLIC OF CHINA] declare at our sole responsibility that following products [Infrared Thermometer, Model: KF-HW-001, KF-HW-002, KF-HW-003, KF-HW-004, KF-HW-005, risk classification - Class IIa] comply with requirements of Directive 93/42/EEC [and other harmonized laws and regulations].
The products comply with requirements of relevant harmonized standards [EN 60601-1, EN 60601-1-2, IEC 60601-1-11, ISO 80601-2-56]
Notified body [TÜV SÜD Product Service GmbH Zertifizierstellen, 0123] has performed [description of conformity assessment procedure] and issued the certificate [G1 101949 0002 Rev. 02] .
The manufacturer is exclusively responsible for the DOC. All supporting documentations retained under the premises of the manufacturer.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

NOTIFIED BODY: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Germany

NOTIFIED BODY *NUMBER: 0123*

(EC) CERTIFICATE(S): G1 101949 0002 REV. 02

EC REP SUNGO EUROPE B.V.
Olympisch Stadion 24, 1076 DE Amsterdam

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: Changsha *CITY, DATE 2021.05.15*

SIGNATURE: _____

NAME: WEI XIANJUN

POSITION: Management Representative

Applied Standards List

No.	Title of the standard	Reference of the standard	Full or partial compliance
1	MDD 93/42/EEC	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices	Full
2	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufactures and notified bodies	Full
3	MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System	Full
4	RoHS Directive 2011/65/EU Annex II	On the restriction of the use of certain hazardous substances in electrical and electronic equipment	Full
5	EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device Labels, labelling and information to be supplied - Part 1: General requirements	Full
6	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices	Full
7	EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing	Full
8	EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-5:2009	Full
9	EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity ISO 10993-10:2010	Full
10	EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes	Full
11	EN ISO 14971:2012	Medical devices – Application of risk management to medical devices	Full
12	EN 60601-1:2006/ A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005/A1:2012	Full
13	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	Full
14	IEC 60601-1-11:	Medical electrical equipment - Part 1- 11: General requirements	Full

No.	Title of the standard	Reference of the standard	Full or partial compliance
	2015	for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-11:2015	
15	EN ISO 80601-2-56: 2017	Medical electrical equipment - Part 2- 56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement ISO 80601-2-56: 2017	Full
16	IEC 62304:2006/A1: 2015	Medical device software – Software life cycle processes IEC 62304:2006/A1:2015	Full
17	EN 60601-1-6:2010/ A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010/A1:2013	Full
18	IEC 62366-1:2015	Medical devices - Part 1 - Application of usability engineering to medical devices	Full