

Declaration of Conformity

Manufacturer: Dongguan SIMZO Electronic Technology Co.Ltd.

Address: No.6, Zhangzhou Road, Daojiao Town, Dongguan City, Guangdong Province, 523187, P.R.China.

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg Germany

Product: Infrared Thermometer

Models: HW-1, HW-2, HW-2S, HW-3, HW-4, HW-4S, HW-302, HW-303, HW-F1, HW-F2, HW-F3, HW-F4, HW-F5, HW-F6 and HW-F7

Classification: II a (rule 10 of Annex IX of MDD 93/42/EEC)

UMDNS: 14036

GMDNS: 14036

Conformity assessment route: Annex V of MDD 93/42/EEC.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and notify body.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) and amended by directive 2007/47/EC.

On the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast):
DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011.

Standard list:

EN ISO 13485:2016 EN ISO 15223-1:2016 EN 1041:2008 EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN ISO 14971:2012 EN 60601-1:2006/A1:2013

EN 60601-1-2:2015 EN 60601-1-6:2010 EN 60601-1-11:2015

EN ISO 80601-2-56:2017 EN 62304:2006/AC:2008 EN 62366-1:2015 EN ISO 780:2016

Notified Body: SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

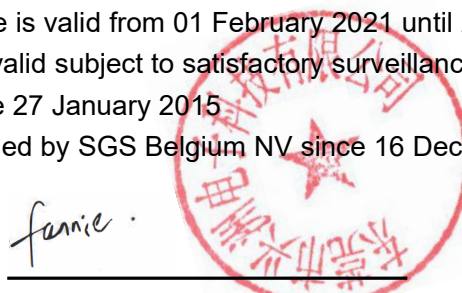
t +32(0)3 3545-48-48 f +32 (0)3 545-48-49 www.sgs.com

(EC) Certificate: CN19/41053

This certificate is valid from 01 February 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Certified since 27 January 2015

and first certified by SGS Belgium NV since 16 December 2019.

Signature: 

Date: Feb. 02, 2021