EU Declaration of Conformity
Revision: A
Number: A-H56000R20W9A

EU Declaration of Conformity

Equipment:

Product Brand:	Motorola
Product Model Number:	TE-93
Product Type:	Infrared Thermometer
***Supplied Accessories:**	2 x AA 1.5v Alkaline Batteries

*Not covered by the defined Conformity Assessment Certificate# G1 068757 0047.

Product Classification:	Class IIa by Rule 10 according to Annex IX of Directive 93/42/EEC
UMDNS Code and Name:	14036 Thermometer, Infrared

We, Meizhou Guo Wei Electronics Co., Ltd of AD1 Section, The Economy Development Area, Dongsheng Industrial Area, Meizhou, 514000, Guangdong Province, P.R. China, declare under our sole responsibility that the above referenced product complies with the following:

Directives:	**Medical Devices Directive:**	93/42/EEC
	RoHS:	2011/65/EU and amendment (EU) 2015/863
	Conformity Assessment Procedure:	Annex II – excluding Section 4

The notified body TÜV SÜD Product Service GmbH, located at Ridlerstraße 65, 80339 MÜNCHEN, Germany, identification number 0123, issued in the course of the mentioned conformity assessment procedure the following certificate:

Conformity Assessment Certificate Number and Validity: G1 068757 0047 valid until 20 August 2023

The following standards have been applied:

Safety & Health:	EN 60601-1:2006 + A1:2013 + A12:2014 EN 60601-1-2:2015 EN 60601-1-11:2015 EN ISO 80601-2-56:2017 + A1:2020

Additional Compliance:

REACH Annex XV:	(EC) No 1907/2006
REACH Annex XVII:	(EC) No 1907/2006 Entries 20 and 50
POP:	(EU) 2019/1021
WEEE:	2012/19/EU
Packaging and Waste:	94/62/EC

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Additional Information:

Manufacturer:	Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd
Manufacturer Address:	702/704, Block C, Tsinghua Unis Science Park, No. 13 Langshan Rd, Hi-Tech Industrial Park (North), Nanshan District, 518057, Shenzhen, P.R. China.
EU Authorised Representative:	Wellkang Ltd, Suite B, 29 Harley Street, London, W1G 9QR. United Kingdom.
Quality Certificates Issued	The manufacturer is certified by TÜV SÜD Product Service GmbH to the following: **EC Certificate:** Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) Certificate Number: G1 068757 0047 Rev. 00 **QS Certificate:** EN ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes Certificate Number: Q5 068757 0048 Rev. 00 Copies of the certificates are available upon request.

Signed for and on behalf of Meizhou Guo Wei Electronics Co., Ltd

Place: Shenzhen, P.R. China **Date:** 04 September 2020

Name:	**Function/Title:**	**Signature:**
Raymond Leung	Chief Technical Officer