EC Declaration of Conformity

Manufacturer:

Geon Corporation
No. 12, Gung Ye Road, Hsi Hu,
Chang Hwa Hsien, Taiwan, ROC

whose single Authorized Representative:

MYM STC, SL.
Avda. de los Rosales, 32
28935 Móstoles, Madrid (España)

We, the manufacturer, herewith declare that the products

Digital thermometer

*(*including system components and accessories*)*

UMDNS-Code: **14032** / *GMDN Code:* **14032**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX rule 10 of the Directive 93/42/EEC. It bears the mark

CE 2460

The product concerned has been manufactured under a quality management system according to Annex II excluding section 4 of Council Directive 93/42/EEC, as amended by 2007/47/EC and the essential requirement of Annex I pertaining to medical devices. For applicable standards and product list/schedule, please refer to Appendix I and Appendix II.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

DNV GL PRESAFE AS
Veritasveien 3,
1363 Høvik, Norway

Certificate No.: 10000328121-PA-NA-TWN
Issue date: 25 May 2020
Expiry date: 24 May 2024

The above mentioned declaration of conformity is sole/exclusively under the responsibility of

Geon Corporation

Hsi Hu, 2020/04/13
Place , date

General Manager

Appendix I – Applicable Standards

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN ISO 13485:2016	Medical devices – Quality management system – Requirements for regulatory purpose
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
EN 12470-3: 2000+A1:2009	Clinical thermometers – Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Symbols for use in the labeling of medical devices
EN 60601-1: 2006 + A1: 2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-6: 2010/A1: 2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 10993-1: 2009 + AC:2010	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 14971: 2012	Medical devices. Application of risk management to medical devices
EN 62366: 2008 + A1: 2015	Medical devices — Application of usability engineering to medical devices
EN 62366-1: 2015	Medical devices — Part 1: Application of usability engineering to medical devices
EN 62304: 2006 / A1:2015	Medical device software — Software life cycle processes
EN ISO 17664:2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ASTM E1112: 00	Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
EN 50581: 2012 ROHS	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 50419: 2006 WEEE	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)

Appendix II – Product Listing/Schedule

Series	Model Number	Description/Name	GMDN Code
102	MT-B112	Clinical Thermometer, display unit 0.1°C	14032
	MT-B122	Clinical Thermometer, display unit 0.1°C	14032
	MT-B132	Clinical Thermometer, display unit 0.1°C	14032
	MT-B132A	Clinical Thermometer, display unit 0.1°C	14032
	MT-B132F	Clinical Thermometer, display unit 0.1°C	14032
	MT-B162	Clinical Thermometer, display unit 0.1°C	14032
	MT-B162A	Clinical Thermometer, display unit 0.1°C	14032
	MT-B172	Clinical Thermometer, display unit 0.1°C	14032
	MT-B182	Clinical Thermometer, display unit 0.1°C	14032
	MT-OR	Clinical Thermometer, display unit 0.1°C	14032
	MT-B331C	Clinical Thermometer, display unit 0.1°C	14032
	MT-B120	Clinical Thermometer, display unit 0.1°C	14032
	MT-B1708	Clinical Thermometer, display unit 0.1°C	14032
	MT-B117	Clinical Thermometer, display unit 0.1°C	14032
	MT-B127	Clinical Thermometer, display unit 0.1°C	14032
	MT-B130	Clinical Thermometer, display unit 0.1°C	14032
	MT-B132FA	Clinical Thermometer, display unit 0.1°C	14032
	MT-B132FB	Clinical Thermometer, display unit 0.1°C	14032
	MT-B1010F	Clinical Thermometer, display unit 0.1°C	14032
201	MT-B221	Clinical Thermometer, display unit 0.01°C	14032
	MT-B231	Clinical Thermometer, display unit 0.01°C	14032
	MT-B231A	Clinical Thermometer, display unit 0.01°C	14032
	MT-B231F	Clinical Thermometer, display unit 0.01°C	14032
	MT-B261	Clinical Thermometer, display unit 0.01°C	14032
	MT-B261A	Clinical Thermometer, display unit 0.01°C	14032
	MT-B281	Clinical Thermometer, display unit 0.01°C	14032
	MT-OR2	Clinical Thermometer, display unit 0.01°C	14032