

EU DECLARATION OF CONFORMITY

We, Terumo Medical Products(Hangzhou) Co.,Ltd,
M4-9-5 Hangzhou Economic & Technological Development Zone,
310018 Hangzhou, People's Republic of China

with Single Registration Number of (SRN): CN-MF-000001640

being the manufacturer of:

TERUMO DIGITAL CLINICAL THERMOMETER

Intended purpose: Terumo Digital Clinical Thermometer is intended in use for body temperature measurement in hospital ward and clinic. ET*C207S is for axillary and ET*C407S is for oral (sublingual) / rectal use. When ET*C407S is in oral use, the target age is for those over 5 years old.

Basic UDI-DI: 69276755ETC79

Related product codes: See Appendix (full list of active codes)

Declare that the above product of Class IIa is in conformity with applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the "Conformity assessment based on a quality management system and on assessment of technical documentation" set out in Annex IX, and by certification of Annex IX.3 (EU quality management system certificate number: G10 037584 0029), under the supervision of [TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany] as Notified Body authorized by the [Germany] Competent Authority and carrying the Notified Body NO.[0123].

We furthermore declare that the above product is in conformity with the provisions of [other regulations are not included in MDR regulation.(if applicable, specify the detailed regulation. If not applicable, omit this section.)

Following Common Specifications have been used within the conformity assessment for Regulation (EU) 2017/745: (if applicable, specify the detailed Common Specification. If not applicable, omit this section.)

Authorised Representative: TERUMO EUROPE N.V.,
Interleuvenlaan 40,3001 LEUVEN, BELGIUM
Authorized representative SRN: BE-AR-000001433

This EU declaration of conformity is issued under our sole responsibility.

Hangzhou 2024.05.28

(Place, Date of Issue)

Hui Weng

Hui Weng

Person responsible for regulatory compliance

[Terumo Medical Products (Hangzhou) Co.,Ltd]

Appendix - Related product codes

Appendix : Related product codes

Brand Name	Model number
TERUMO DIGITAL CLINICAL THERMOMETER	ET*C207S
	ET*C407S