

DECLARATION OF CONFORMITY

SUPPLIER INFORMATION

Company name: LIEWOOD A/S

Company Address: Blegdamsvej 124, 2100 Copenhagen Ø, Denmark

Contact Number: +45 3117 0897

PRODUCT INFORMATION

Style Name: Olivier Digital Thermometer

Style Number: LW19298

Quality: Base Unit: 100% ABS; Sleeve: 100% Silicone



Color code: 5060

Color name: Sandy

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The object of the declaration described above is in conformity with EU Regulation 2017/745 (Class IIA, Rule 10).

Identification number: 0123

Notified body: TÜV SÜD Product Service GmbH, Westendstrasse 199, 80686 Munich, Germany

(EC) Certificate(s): G10 078672 0022 Rev. 00

European Representative: WellKang Ltd (www.CE-marking.eu), Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland

SRN: XI-AR-000001836

EMDN code: V03010102

Basic UDI-DI: 69538259UIT9G

IEC 60601-1:2012 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 compatibility - Requirements and tests
EN 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential
performance - Collateral standard: Usability IEC 60601-1-6:2010
EN 60601-1-11:2015 IEC 6060-1-11:2012+A1:2012 Medical electrical equipment - Part 1-11: 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
ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 1041:2008 Information supplied by the manufacturer with medical devices
EN 62366:2008 Medical devices - Application of usability engineering to medical devices
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
EN 62304:2015 Medical device software - Software life-cycle processes
EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 780:2015 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages
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

Place and date of issue: Copenhagen, 20-11-2025

Name and title of authorised person: Sonja Braun, Compliance Specialist

Signed on behalf of LIEWOOD A/S:

