

# DECLARATION OF CONFORMITY

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## 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](http://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 60601-1-11:2012+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, 31-07-2024

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

**Signature:**

