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PAUL HARTMANN AG, P.O. Box 1420, 89504 Heidenheim, Germany

EU Declaration of Conformity Class IIa

Heidenheim, 2024-03-20

We herewith declare under our sole responsibility that the class IIa medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (6) and Annex IX have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G10 011858 0065.

Radio Equipment Directive, 2014/53/EU
We herewith declare under our sole responsibility that the objects of the declaration satisfy the applicable provisions of the Radio Equipment Directive 2014/53/EU. The conformity assessment procedure according to Article 17 (2b) and Annex III has been performed and the Technical Documentation is kept available.
The conformity assessment procedure is under the supervision of the Notified Body Intertek Semko A, Torshamnsgatan 43, 164 22 Kista, Sweden 0413,
EU Type-examination Certificate No.: SE-RED-2001958 Ed. 1

The objects of the declaration also comply with the following relevant, harmonized standards, or with the technical specifications in relation to which conformity is declared:

- EN 300 328:2019 V2.2.2

Wideband transmission systems - Data transmission equipment operating in 2,5 GHz band - Harmonised Standards for access to radio spectrum

- EN 301 489-1:2019 V2.2.3

Electromagnetic Compatibility (EMC) standard for radio equipment and services - Part 1: Common technical requirements - Harmonised standards for Electromagnetic Compatibility

- EN 301 489-17:2020 V3.2.4

Electromagnetic Compatibility (EMC) standard for radio equipment and services - Part 17: Specific conditions for Broadband and Wideband Data Transmission Systems - Harmonised Standard for Electromagnetic Compatibility

- EN IEC 62368-1:2020

Audio/video, information and communication technology equipment - Part 1: Safety requirements (IEC 62368-1:2018)

- EN 62479:2010

Assessment of the compliance of low power electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) (IEC 62479:2010, modified)

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Device Group	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS		
Intended Purpose	Non-sterile, non-implantable, active medical devices for monitoring of vital physiological parameters		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Veroval duo control	2259	10 (3)	40495002259KR

PAUL HARTMANN AG

ppa.

François Georgelin
Member of the Management Board

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2024-06-30