

PAUL HARTMANN AG
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Germany

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EU Declaration of Conformity Class IIa

Heidenheim, 2023-09-20

We herewith declare under our sole responsibility that the class IIa medical device 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.

RoHS Directive, 2011/65/EU

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 IEC 63000:2018
Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB
661090

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Helps. Cares. Protects.

PAUL HARTMANN AG

ppa.

François Georgelin

Member of the Management Board

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

GLN 404 9500 00000 0

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