PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	2259
Manufacturer	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim GERMANY

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

Applied legislative acts

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Non-sterile, non-implantable, active medical devices for monitoring of vital physiological parameters	
Classification	Risk Class	Rule
	Class IIa	Rule 10 | 1st paragraph + 3rd indent main case
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: Z120302 - VITAL SIGNS MONITORING INSTRUMENTS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002259KR	
	Code	Term
EMDN	Z120302	VITAL SIGNS MONITORING INSTRUMENTS
GMDN	45617	Automatic-inflation electronic sphygmomanometer, portable, arm/wrist
UMDNS	16-173	Sphygmomanometers, Electronic, Automatic

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Radio Equipment Directive 2014/53/EU

Conformity Assessment Procedure	Article 17 (2a) and Annex II
Notified Body	Intertek Semke A, Torshamnsgatan 43, 164 22 Kista, Sweden 0413
EU Type-examination Certificate	SE-RED-2001958 Ed. 1
Applicable Harmonised Standards	
EN 300 328:2019 V2.2.2	Wideband transmission systems - Data transmission equipment EN 300 328:2019 V2.2.2 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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ppa.

Jochen Bauer
Vice President R&D Wound Care & Consumer Health

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid from: 2025-05-06
Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
703494	Veroval DUO Control
900107	Veroval Duo ControlM_GiftBox
925501	Veroval duo control medium SK1 P1
925502	Veroval duo control medium SK2 P1
925503	Veroval duo control medium SK3 P1
925504	Veroval duo control medium SK4 P1
925505	Veroval duo control medium SK5 P1
925506	Veroval duo control medium SK6 P1
925521	Veroval duo control large SK1 P1
925522	Veroval duo control large SK2 P1
925523	Veroval duo control large SK3 P1
925524	Veroval duo control large SK4 P1
925525	Veroval duo control large SK5 P1
925526	Veroval duo control large SK6 P1
9256020	Veroval duo control M giftbox Belgium
9256021	Veroval duo control M giftbox Belgium
9256220	Veroval duo control L giftbox Belgium

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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