

## EU Declaration of Conformity

Heidenheim, 2025-04-09

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 3630                                                                     |
| <b>Manufacturer</b>         | PAUL HARTMANN AG<br>Paul-Hartmann-Str. 12<br>89522 Heidenheim<br>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 legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

### Applied legislative act

#### 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: V030101 - THERMOMETERS |                                                |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                                                                    |                                                |
| Basic UDI-DI                    | 40495003630KU                                                                                                    |                                                |
| EMDN                            | Code                                                                                                             | Term                                           |
|                                 | V030101                                                                                                          | THERMOMETERS                                   |
| GMDN                            | 17888                                                                                                            | Infrared patient thermometer, skin             |
| UMDNS                           | 14-036                                                                                                           | Thermometers, Infrared                         |

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

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PAUL HARTMANN AG

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**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                       |
|--------|------------------------------------------|
| 900070 | Veroval Baby promotion socks             |
| 925071 | Veroval baby SK1 P1                      |
| 925072 | Veroval baby SK2 P1                      |
| 925073 | Veroval baby SK3 P1                      |
| 925074 | Veroval baby SK4 P1                      |
| 925075 | Veroval baby SK5 P1                      |
| 925121 | Veroval baby LG1 Colour Promotion Red    |
| 925122 | Veroval baby LG2 Colour Promotion Red    |
| 925123 | Veroval baby LG3 Colour Promotion Red    |
| 925131 | Veroval baby LG1 Colour Promotion Blue   |
| 925132 | Veroval baby LG2 Colour Promotion Blue   |
| 925133 | Veroval baby LG3 Colour Promotion Blue   |
| 925141 | Veroval baby LG1 Colour Promotion Green  |
| 925142 | Veroval baby LG2 Colour Promotion Green  |
| 925151 | Veroval baby LG1 Colour Promotion Yellow |
| 925152 | Veroval baby LG2 Colour Promotion Yellow |

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