

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	2067
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 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 3rd indent
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. 03, Device Group: V030101 - THERMOMETERS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002067KE	
EMDN	Code	Term
	V030101	THERMOMETERS
GMDN	14035	Intermittent electronic patient thermometer
UMDNS	14-032	Thermometers, Electronic

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PAUL HARTMANN AG

ppa.

A blue ink signature of Jochen Bauer, consisting of a large, stylized 'J' followed by a series of loops and a final 'B'.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

A blue ink signature of Stefan Fischer, featuring a stylized 'S' and 'F' followed by a series of loops.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2025-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
925031	Thermoval Rapid SK1 P1
925032	Thermoval Rapid SK2 P1
925033	Thermoval Rapid SK3 P1
925034	Thermoval Rapid SK4 P1

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