

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	2070
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 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	40495002070K3	
EMDN	Code	Term
	V030101	THERMOMETERS
	GMDN	14035
	UMDNS	14-032
		Intermittent electronic patient thermometer
		Thermometers, Electronic

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

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
925051	Thermoval Kids Flex SK1 P1
925052	Thermoval Kids Flex SK2 P1
925053	Thermoval Kids Flex SK3 P1
925054	Thermoval Kids Flex SK4 P1

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