

EU Declaration of Conformity

Heidenheim, 2025-07-24

Product Group Number	1394
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	Single-use, non-active, non-implantable devices for wound and skin care.	
Classification	Risk Class	Rule
	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Notified Body	n.a.	
Basic UDI-DI	40495001394KR	
EMDN	Code	Term
	M040299	Non-adhesive absorbent dressing - other
GMDN	40545	Menstrual pad, unscented
UMDNS	15-216	Dressings, Other

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

Stefan Grote
Member of the Management Board

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Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2030-07-24

List of products falling under the respective Product Group Number:

REF	Name - Description
716212	Samu® Classic MIDI P56
716213	Samu® Classic MAXI P56
716214	Samu® Classic MAXI P10
716221	Samu® Classic MINI P20
716313	Samu® Plus MAXI P56
716325	Samu® Plus MAXI P10

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