

EU Declaration of Conformity

Heidenheim, 2026-03-31

Product Group Number	3364
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	General single-use, non-active, non-implantable devices used in health care	
Classification	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003364KW	
	Code	Term
EMDN	T020402	Reinforced Surgical Gowns
GMDN	35091	Surgical gown, single-use
UMDNS	11-901	Gowns; Operating room; Disposable

PAUL HARTMANN AG
ppa.



Martin Walther
Head of Business Division
Risk Prevention

Valid from: 2026-03-31
Valid until: 2030-06-30

i.V.



Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

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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List of products falling under the respective Product Group Number: **3364**

REF	Name - Description
890595	Foliodress Gown Comfort Reinforced, L
890605	Foliodress Gown Comfort Reinforced, XL
890615	Foliodress Gown Comfort Reinforced, XXL
992881	Foliodress Gown Comfort Reinforced, XL, P420
992882	Foliodress Gown Comfort Reinforced, XXL, P400
302036	Foliodress Gown Comfort Reinforced, L
302037	Foliodress Gown Comfort Reinforced, XL
302039	Foliodress Gown Comfort Reinforced, XXL

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