

EU Declaration of Conformity

Heidenheim, 2026-03-31

Product Group Number	3361
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	40495003361KQ	
	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: **3361**

REF	Name - Description
892417	Foliodress Gown Protect Reinforced, L
892427	Foliodress Gown Protect Reinforced, XL
892437	Foliodress Gown Protect Reinforced, XXL
992946	Foliodress Gown Protect Reinforced, L, P420
992947	Foliodress Gown Protect Reinforced, XL, P420
992948	Foliodress Gown Protect Reinforced, XXL, P360
302057	Foliodress Gown Protect Reinforced, M
302027	Foliodress Gown Protect Reinforced, L
302028	Foliodress Gown Protect Reinforced, XL
302030	Foliodress Gown Protect Reinforced, XXL

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