

EU Declaration of Conformity

Heidenheim, 2026-03-31

Product Group Number	3360
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	40495003360KN	
	Code	Term
EMDN	T020401	Standard 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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Helps. Cares. Protects.

List of products falling under the respective Product Group Number: **3360**

REF	Name - Description
892327	Foliodress Gown Protect Standard, M
892377	Foliodress Gown Protect Standard, L
892387	Foliodress Gown Protect Standard, XL
892397	Foliodress Gown Protect Standard, XXL
992893	Foliodress Gown Protect Standard, M, P600
992894	Foliodress Gown Protect Standard, L, P600
992895	Foliodress Gown Protect Standard, XL, P480
992896	Foliodress Gown Protect Standard, XXL, P480
302009	Foliodress Gown Protect Standard, M
302013	Foliodress Gown Protect Standard, L
302024	Foliodress Gown Protect Standard, XL
302025	Foliodress Gown Protect Standard, XXL

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