

EU Declaration of Conformity

Heidenheim, 2026-03-31

Product Group Number	3363
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	40495003363KU	
	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

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

i.V.



Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

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: **3363**

REF	Name - Description
890945	Foliodress Gown Comfort Standard, L
890955	Foliodress Gown Comfort Standard, XL
890965	Foliodress Gown Comfort Standard, XXL
992873	Foliodress Gown Comfort Standard, L, P600
992874	Foliodress Gown Comfort Standard, XL, P480
302033	Foliodress Gown Comfort Standard, L
302034	Foliodress Gown Comfort Standard, XL
302035	Foliodress Gown Comfort Standard, XXL

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