PAUL HARTMANN AG
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89522 Heidenheim

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Germany

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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-11-20

Product Group Number	3351
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 Is	Rule 1
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility (a)	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Production Quality Assurance Certificate No. G26 011858 0077 Rev. 00 Device Group T020402 - REINFORCED SURGICAL GOWNS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003351KM	
	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

i.V.

Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2025-11-30
Valid until: 2030-11-29

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: 3351

REF	Name - Description
992937	Foliodress Gown Comfort Urology Ultra Reinforced L Disposable surgical gown made of non-woven material with fluid-impermeable PE film and reinforced sleeves
992938	Foliodress Gown Comfort Urology Ultra Reinforced XL Disposable surgical gown made of non-woven material with fluid-impermeable PE film and reinforced sleeves

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:
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