

## EU Declaration of Conformity

Heidenheim, 2025-11-20

<b>Product Group Number</b>	1264
<b>Manufacturer</b>	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 T0299 – Protection drapes and garments - other	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001264KB	
	Code	Term
EMDN	T0299	Protection drapes and garments - others
GMDN	35492	Isolation gown, single-use
UMDNS	15-037	Gowns; Isolation

PAUL HARTMANN AG

ppa.



**Martin Walther**

Head of Business Division  
Risk Prevention

Valid from: 2025-11-30

Valid until: 2030-11-29

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: 1264

REF	Name - Description
992167	Foliodress S isolation gown Disposable isolation gown made of blue non-woven material

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, Oliver Neubrand  
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