

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info



EU Declaration of Conformity Class Is

Heidenheim, 2023-06-01

We herewith declare under our sole responsibility that the Class I sterile medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) and Annex XI part A with respect to sterility have been performed and the Technical Documentation is kept available.

The sterilization processes are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G21 011858 0069.

Device Group	T0299 Protection drapes and garments - other		
Device Properties	MDS 1005.1 Ethylene Oxide Sterilization		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Foliodress gown Comfort Basic	1251	1	40495001251K2
Foliodress gown Comfort Standard	1253	1	40495001253K6
Foliodress gown Comfort Reinforced	1254	1	40495001254K8
Foliodress gown Protect Standard	1258	1	40495001258KG
Foliodress gown Comfort Standard P&G	3347	1	40495003347KW
Foliodress gown Comfort Extra Reinforced	3348	1	40495003348KY
Foliodress gown Comfort Extra Reinforced P&G	3349	1	40495003349L2
Foliodress gown Comfort Extra Reinforced Model B	3350	1	40495003350KK
Foliodress gown Comfort Extra Urology	3351	1	40495003351KM

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
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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Device Group	T0299 Protection drapes and garments - other		
Device Properties	MDS 1005.1 Ethylene Oxide Sterilization		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Foliodress gown Protect Basic	3344	1	40495003344KQ
Foliodress gown Protect Standard	3345	1	40495003345KS
Foliodress gown Protect Reinforced	3346	1	40495003346KU
Foliodress Comfort Extra Reinforced	3356	1	40495003356KX
Foliodress arm cover sterile	3395	1	40495003395L9

PAUL HARTMANN AG

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Martin Walther
Senior Vice President Risk Prevention

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Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

GLN 404 9500 00000 0

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