

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](http://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.

<b>Device Group</b>	T0399 - Protection devices (Excluding Personal Protective Equipment PPE) - other		
<b>Device Properties</b>	MDS 1005.1 Ethylene Oxide Sterilization		
<b>Product Name</b>	<b>Product Group Number</b>	<b>Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)</b>	<b>Basic UDI-DI</b>
Foliodrape Fenestrated Drapes adhesive Protect sterile	2141	1	40495002141JZ

PAUL HARTMANN AG

ppa.

**Martin Walther**  
Senior Vice President Risk Prevention

ppa.

**Stefan Fischer**  
Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

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: Commercial Register of the District Court of Ulm file no. HRB  
Fritz-Jürgen Heckmann

Sitz Heidenheim  
Amtsgericht Ulm HRB 661090  
Registered Office Heidenheim  
661090