

PAUL HARTMANN AG  
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Germany

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[www.hartmann.info](http://www.hartmann.info)



## EU Declaration of Conformity

Heidenheim, 2022-08-17

### Manufacturer Information:

Manufacturer: PAUL HARTMANN AG  
Single Registration Number (SRN): DE-MF-000005861

We hereby declare under our sole responsibility that the medical devices listed below comply with the applicable provisions of the

- General Safety and Performance Requirements (Annex I) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices

### Objects of this Declaration:

Objects	Product Name(s)	Basic UDI-DI
1805	VivanoTec Y-Connector	40495001805KR

### (High-Level) Intended Purpose and Device Nomenclature

Single-use, non-active, non-implantable devices for wound and skin care

Nomenclature	Code	Term
EMDN	A0699	Drainage and fluid collection devices - other
GMDN	47409	Negative-pressure wound therapy tubing set
UMDNS	11-307	Drains, T

The objects of the declaration have been qualified as medical devices, and the risk classification has been determined according to the classification rules in Annex VIII of Regulation (EU) 2017/745. The risk classification, the classification rule and the conformity assessment procedure used to demonstrate conformity are listed below. The technical documentation is kept available.

Risk Classification	Classification Rule	Conformity Assessment Procedure
Is	1	Article 52(7) and Annex XI

ILN 040 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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The conformity assessment procedure is under the supervision of the Notified Body:  
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123.

### Relevant Certificates

EU QMS Certificate(s) (MDR): G21 011858 0069 Rev. 02, Class Is

ISO QMS Certificate(s): Q5 011858 0062 Rev. 02, EN ISO 13485:2016

PAUL HARTMANN AG

ppa.

François Georgelin

Member of the Management Board

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2023-03-01

ILN 040 9500 00000 0

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