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Helps. Cares. Protects.

Consolidated EU Declaration of Conformity for Medical Devices in Classes IIa, IIb & III

Heidenheim, 01. March 2022

We herewith declare under our sole responsibility that the class IIa, IIb and III 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 (6) and Annex IX for class IIa devices, according to Article 52 (4) and Annex IX for class IIb devices, according to Article 52 (3) and Annex IX for class III devices have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G10 011858 0065.

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

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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Class IIb medical devices in conjunction with the EU Quality Management System Certificate (MDR)
No. G10 011858 0065

Device Group	M040499 – Dressings for wounds, sores and ulcerations - others		
Intended Purpose	Single-use, sterile, non-medicated dressings suitable for the treatment of wounds		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Atrauman	1384	4 (2)	40495001384KN
Atrauman Silicone	1390	4 (2)	40495001390KH
Grassolind neutral	1382	4 (2)	40495001382KJ
HydroClean	3198	4 (2)	40495003198L5
HydroClean advance	2585	4 (2)	40495002585L9
HydroClean advance cavity	3218	4 (2)	40495003218KJ
HydroClean advance mini	2841	4 (2)	40495002841L4
HydroClean cavity	3199	4 (2)	40495003199L7
HydroClean mini	2850	4 (2)	40495002850L5
Hydrocoll	1815	4 (2)	40495001815KU
Hydrocoll basic	1815	4 (2)	40495001815KU
Hydrocoll concave	1815	4 (2)	40495001815KU
Hydrocoll sacral	1815	4 (2)	40495001815KU
Hydrocoll thin	1815	4 (2)	40495001815KU
HydroTac	1830	4 (2)	40495001830KQ
HydroTac Comfort	1832	4 (2)	40495001832KU
HydroTac Concave	1831	4 (2)	40495001831KS
HydroTac Sacral	1833	4 (2)	40495001833KW
Hydrotac transparent	3612	4 (2)	40495003612KS
Hydrotac transparent Comfort	3613	4 (2)	40495003613KU
RespoSorb Silicone	2493	4 (2)	40495002493L3
RespoSorb Silicone Border	2842	4 (2)	40495002842L6
RespoSorb Super	1326	4 (2)	40495001326K8
Zetuvit Plus	1407	4 (2)	40495001407K9
Zetuvit Plus Silicone	2186	4 (2)	40495002186KP
Zetuvit Plus Silicone Border	2843	4 (2)	40495002843L8

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