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

Heidenheim, 01. March 2021

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 (Registration Number DE/0000007683 [BfArM]), 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

Dr. Raymund Heinen
CPO

ppa.

Stefan Fischer
Head of Regulatory Affairs

Valid until: 2022-03-01

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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
HydroTac	1830	4 (2)	40495001830KQ
HydroTac Concave	1831	4 (2)	40495001831KS
HydroTac Comfort	1832	4 (2)	40495001832KU
HydroTac Sacral	1833	4 (2)	40495001833KW
Hydrotac transparent	3612	4 (2)	40495003612KS
Hydrotac transparent Comfort	3613	4 (2)	40495003613KU
RespoSorb Super	1326	4 (2)	40495001326K8
RespoSorb Silicone	2493	4 (2)	40495002493L3
RespoSorb Silicone Border	2842	4 (2)	40495002842L6
Zetuvit Plus	1407	4 (2)	40495001407K9
Zetuvit Plus Silicone	2186	4 (2)	40495002186KP
Zetuvit Plus Silicone Border	2843	4 (2)	40495002843L8

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, 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