

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1152
Manufacturer	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim GERMANY

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

Applied legislative act

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 4 main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001152JX	
EMDN	Code	Term
	M020102	COTTON GAUZES, FOLDED
GMDN	48134	Woven gauze pad
UMDNS	10-966	Kompresse, Mull (Compresses, gauze)

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
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

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



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PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

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List of products falling under the respective Product Group Number:

REF	Name - Description
205005	Sterilux ES swabs nst 5x5 21th 8ply (RU)
205007	SteriluxES swabs nst 10x10 21t 8p (RU)
205008	SteriluxES swabs nst 10x20 21t 8p (RU)
416800	Sterilux ES ust 5x5 8f 13fd P100
416801	Sterilux ES ust 5x7,5 8f 13fd P100
416802	Sterilux ES ust 7,5x7,5 8f 13fd P100
416803	Sterilux ES ust 7,5x10 8f 13fd P100
416804	Sterilux ES ust 10x10 8f 13fd P100
416808	Sterilux ES ust 10x10 12f 13fd P100
416812	Sterilux ES ust 10x10 16f 13fd P100
418800	Sterilux ES-Kompr ust 5x5 8f 17fd P100
418801	Sterilux ES ust 5x7,5 8f 17df P100 Sterilux ES ust 5x7,5 8f 17fd P100
418802	Sterilux ES ust 7,5x7,5 8f 17fd P100
418803	Sterilux ES nst 7,5x10 8p 17th P100
418804	Sterilux ES-Kompr ust 10x10 8f 17fd P100
418805	Sterilux ES-Kompr ust 10x20 8f 17fd P100
418806	Sterilux ES-Kompr ust 5x5 12f 17fd P100
418807	Sterilux ES nst 7,5x7,5 12p 17th P100
418809	Sterilux ES ust 10x10 12f 17fd P100
418810	Sterilux ES-Kompr ust 10x20 12f17fd P100
418811	Sterilux ES-Kompr ust 5x5 16f 17fd P100
418812	Sterilux ES ust 7,5x7,5 16f 17fd P100
418813	Sterilux ES-Kompr ust 10x10 16f17fd P100
418814	Sterilux ES ust 15x15 16f 17fd P100
418815	Sterilux ES-Kompr ust 10x20 16f17fd P100
481005	Sterilux ES ust 10x10 12f 13fd P100
481006	Sterilux ES ust 5x5 8f 13fd P100
481007	Sterilux ES ust 10x10 8f 13fd P100
481008	Sterilux ES ust 7,5x7,5 8f 13fd P100

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