

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1195
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	Single-use, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class IIa	Rule 7 main paragraph
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M020102 - COTTON GAUZES, FOLDED	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001195KH	
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

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PAUL HARTMANN AG

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Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
205009	Sterilux ES st 7,5x7,5 17t 8pl 5xP2(PP)
205016	Sterilux ES-K st 5x5 17thr 8p (40xP1)
205017	Sterilux ES-K st 7,5x7,5 17thr 8p(20xP1)
205019	Sterilux ES-K st 10x10 17thr 8p (12xP1)
205020	Sterilux ES Swabs st 5x5 17th 8p (25xP2)
205021	Sterilux ES K st 7,5x7,5 17th8ply(25xP2)
205022	Sterilux ES K st 10x10 17th8ply (25xP2)
205023	Sterilux ES Swabs st 10x10 21thr 8p 5xP2
205024	Sterilux ES Swabs st 7,5x7,5 21t 8p 5xP2
205025	Sterilux ES Swabs st 5x5 21thr 8p 5xP2
232001	Sterilux ES-K st 5x5 17fd 8f (P3)
232002	Sterilux ES-K st 5x5 17fd 8f (P5)
232003	Sterilux ES-K st 5x5 17fd 8f (P10)
232004	Sterilux ES-K st 5x5 17fd 8f (P20)
232005	Sterilux ES-K st 5x5 17fd 8f (P40)
232006	Sterilux ES-K st 7,5x7,5 17fd 8f (P3)
232007	Sterilux ES-K st 7,5x7,5 17fd 8f (P5)
232008	Sterilux ES-K st 7,5x7,5 17fd 8f (P10)
232009	Sterilux ES-K st 7,5x7,5 17fd 8f (P20)

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232010	Sterilux ES-K st 7,5x7,5 17fd 8f (P40)
232011	Sterilux ES-K st 10x10 17fd 8f (P3)
232012	Sterilux ES-K st 10x10 17fd 8f (P5)
232013	Sterilux ES-K st 10x10 17fd 8f (P10)
232014	Sterilux ES-K st 10x10 17fd 8f (P20)
232015	Sterilux ES-K st 10x10cm 17fd 8f (P40)
232016	Sterilux ES-K st 10x20cm 17fd 8f (P3)
232017	Sterilux ES-K st 10x20cm 17fd 8f (P5)
232018	Sterilux ES-K st 10x20cm 17fd 8f (P10)
232019	Sterilux ES-K st 10x20cm 17fd 8f (P20)
232021	Sterilux ES-K st 5x5 17fd 12f (P3)
232022	Sterilux ES-K st 5x5 17fd 12f (P5)
232023	Sterilux ES-K st 5x5 17fd 12f (P10)
232026	Sterilux ES-K st 7,5x7,5 17fd 12f (P3)
232027	Sterilux ES-K st 7,5x7,5 17fd 12f (P5)
232028	Sterilux ES-K st 7,5x7,5 17fd12f (P10)
232029	Sterilux ES-K st 7,5x7,5 17fd12f (P20)
232030	Sterilux ES-K st 7,5x7,5 17fd12f (P40)
232031	Sterilux ES-K st 10x10 17fd 12f (P3)
232032	Sterilux ES-K st 10x10 17fd 12f (P5)
232033	Sterilux ES-K st 10x10 17fd12f (P10)
232034	Sterilux ES-K st 10x10 17fd 12f (P20)
232035	Sterilux ES-K st 10x10 17fd12f (P40)
232036	Sterilux ES-K st 10x20 17fd 12f (P3)
232037	Sterilux ES-K st 10x20 17fd 12f (P5)
232180	Sterilux ES-swabs st RU 5x5 21th 8p P3 Sterilux ES-Kpr st RU 5x5 21fd 8f (P3)
232181	Sterilux ES-swabs st RU 5x5 21thr 8p P5 Sterilux ES-Kpr st RU 5x5 21fd 8f (P5)
232182	Sterilux ES-swabs st RU 5x5 21thr 8p P10 Sterilux ES-Kpr st RU 5x5 21fd 8f (P10)
232185	Sterilux ES-Kpr st RU 7,5x7,5 21fd 8f P5 Sterilux ES st 7,5x7,5 21thr RU 8f P5
232186	Sterilux ES-Kpr st RU 7,5x7,5 21f 8f P10

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232187	Sterilux ES-Kpr st RU 7,5x7,5 21f 8f P20
232189	Sterilux ES-swabs st RU 10x10 21th 8p P5
232190	Sterilux ES-Kpr st RU 10x10 21fd 8f P10
232191	Sterilux ES-Kpr st RU 10x10 21fd 8f P20
232193	Sterilux ES-swabs st RU 10x20 21th 8p P5
232194	Sterilux ES-Kpr st RU 10x20 8f P10 Sterilux ES-Kpr st RU 10x20 21fd 8f P10
232195	Sterilux ES-Kpr st RU 10x20 8f P20
400402	Sterilux ES-K st 10x20 17T 12p (5xP1)
400845	Sterilux ES-K st 5x5 17thr 8p (40xP5)
400860	Sterilux ES-K st 10x10 8f (30xP5)
400908	Sterilux ES-K st 7,5x7,5 8pl (30xP5)
416223	Sterilux ES-K st 7,5x7,5 13th 8p (100xP2)
416233	Sterilux ES-K st 7,5x7,5 13th 12p (75xP2)
416521	Sterilux ES-K st 5x5 13th 8p (35xP5)
416522	Sterilux ES-K st 5x7,5 13th 8p (35xP5)
416523	Sterilux ES-K st 7,5x7,5 13th 8p (35xP5)
416533	Sterilux ES-K st 7,5x7,5 13th 12p (30xP5)
416535	Sterilux ES-K st 10x10 13th 12p (25xP5)
418023	Sterilux ES-K st 7,5x7,5 17th 8p (15xP10)
418033	Sterilux ES-K st 7,5x7,5 17th 12p (15xP10)
418035	Sterilux ES-K st 10x10 17fd 12f (15xP10)
418045	Sterilux ES-K st 10x10 17fd 16f (10xP10)
418135	Sterilux ES-K st 10x10 17fd 12f (15xP10)
418145	Sterilux ES K st 10x10 17fd 16f (10xP10)
418223	Sterilux ES-K st 7,5x7,5 17fd 8f (75xP2)
418233	Sterilux ES-K st 7,5x7,5 17fd 12f (75xP2)
418235	Sterilux ES-K st 10x10 17fd 12f (75xP2)
418245	Sterilux ES-K st 10x10 17fd 16f (50xP2)
418521	Sterilux ES-K st 5x5 17th 8p (30xP5)
418523	Sterilux ES-K st 7,5x7,5 17th 8p (30xP5)
418524	Sterilux ES-K st 7,5x10 17fd 8f (30xP5)
418533	Sterilux ES st 7,5x7,5 17fd 12f 25xP5
418535	Sterilux ES-K st 10x10 17fd 12f (25xP5)

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418545	Sterilux ES-K st 10x10 17fd 16f (20xP5)
418551	Sterilux ES-K st 5x5 17th 8p (25xP2)
418554	Sterilux ES K st 7,5x7,5 17fd 8f (25xP2)
418557	Sterilux ES-K st 10x10 17fd 8f (25xP2)
418559	Sterilux ES-K st 10x20 17fd 8f (25xP2)
481003	Sterilux ES-K st 10x10 17fd 16f (10xP10)
481011	Sterilux ES-K st 10x10 17fd 12f (75xP2)
481012	Sterilux ES-K st 10x10 17fd 16f (50xP2)
915252	Sterilux ES-K st 5x5 8p (50xP3)
915418	Sterilux ES-K st 7,5x7,5 8pl (40xP3)
916015	Sterilux ES-K st 10x10 8f (40xP3)

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