

EU Declaration of Conformity

according to the EU-Medical Device Directive 2017/745



Wellell Group

SLK Vertriebs GmbH
Am Herdicksbach 18
D-45731 Waltrop

We

SLK Vertriebs GmbH
Deutschland/Germany

Single registration number (SRN): DE-MF-000010037

Basic UDI: 426064753

hereby declare under our sole responsibility that the products listed in Appendix 1 for the following product group:

- SLK Foam Systems

comply with the conformity assessment procedure set out in Annex IV of Regulation (EU) 2017/745 and all applicable essential safety and performance requirements of Annex I are met.

The procedures set out in Annex II and Annex III of the same Regulation were followed.

The classification of the products listed above is carried out in accordance with Annex VIII of the Regulation.

We assure that the products comply with this regulation and, where applicable, other relevant Union legislation.

This declaration is valid for products placed on the market from the date of issue.

This document is valid until: 31.12.2025

Waltrop, 13.11.2024

Place, Date

A handwritten signature in blue ink, appearing to read 'Oliver Otte', positioned above a horizontal line.

Signature: Oliver Otte, Managing Director

Annex 1

SLK Foam Systems

Risk Class: I

GMDN: 12473

Article-ID	Article Name	Basic UDI-DI	Size	Article Description
10064	SLK XXL Foam	(01)4260647530346(21)10064U	100 x 200 x 22 cm	high quality HR foam system
10081	SLK XXL Foam	(01)4260647530353(21)10081U	120 x 200 x 22 cm	high quality HR foam system
10014	SLK FoamCare Comfort 120	(01)4260647530582(21)10014U	90 x 200 x 12 cm	profiled HR foam mattress
10015	SLK FoamCare Comfort 120	(01)4260647530612(21)10015U	100 x 200 x 12 cm	profiled HR foam mattress
10058	SLK FoamCare Comfort 140	(01)4260647530650(21)10058U	90 x 200 x 14 cm	profiled HR foam mattress
10065	SLK FoamCare Comfort 140	(01)4260647530681(21)10065U	100 x 200 x 14 cm	profiled HR foam mattress
10061	SLK NeoCare Basic	(01)4260647530407(21)10061U	90 x 200 x 12 cm	standard care bed mattress
10066	SLK NeoCare Basic	(01)4260647530438(21)10066U	100 x 200 x 12 cm	standard care bed mattress
10067	SLK NeoCare I	(01)4260647530469(21)10067U	90 x 200 x 12 cm	prophylaxis and therapy system
10068	SLK NeoCare I	(01)4260647530490(21)10068U	100 x 200 x 12 cm	prophylaxis and therapy system
10076	SLK NeoCare II	(01)4260647530520(21)10076U	90 x 200 x 12 cm	standard care bed mattress
10077	SLK NeoCare II	(01)4260647530551(21)10077U	100 x 200 x 12 cm	standard care bed mattress
10016	SLK ProfiSoft Comfort 150	(01)4260647530728(21)10016U	90 x 200 x 15 cm	3-layer comfort mattress
10017	SLK ProfiSoft Comfort 150	(01)4260647530759(21)10017U	100 x 200 x 15 cm	3-layer comfort mattress
10079	SLK Silver Sleep	(01)4260647530933(21)10079U	90 x 200 x 14 cm	2-layer comfort mattress
10080	SLK Silver Sleep	(01)4260647530964(21)10080U	100 x 200 x 14 cm	2-layer comfort mattress
10083	SLK Silver Sleep	(01)4260647530995(21)10083U	90 x 220 x 14 cm	2-layer comfort mattress
10084	SLK Silver Sleep	(01)4260647531022(21)10084U	80 x 200 x 14 cm	2-layer comfort mattress
10085	SLK Silver Sleep	(01)4260647531053(21)10085U	120 x 200 x 14 cm	2-layer comfort mattress
10086	SLK Silver Sleep	(01)4260647531084(21)10086U	140 x 200 x 14 cm	2-layer comfort mattress
10018	SLK ViscoCare Comfort 120	(01)4260647530797(21)10018U	90 x 200 x 12 cm	viscoelastic foam system
10019	SLK ViscoCare Comfort 120	(01)4260647530827(21)10019U	100 x 200 x 12 cm	viscoelastic foam system
10020	SLK ViscoCare Comfort 150	(01)4260647530865(21)10020U	90 x 200 x 15 cm	viscoelastic foam system
10021	SLK ViscoCare Comfort 150	(01)4260647530896(21)10021U	100 x 200 x 15 cm	viscoelastic foam system
10063	SLK XXL Foam	(01)4260647530339(21)10063U	90 x 200 x 22 cm	high quality HR foam system

Waltrop, 13.11.2024

Place, Date



Signature: Oliver Otte, Managing Director