

# EU Declaration of Conformity

according to the Directive 93/42/EEG



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 AIK / IPC

comply with the conformity assessment procedure set out in Annex VI of Directive 93/42 EEC 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 IX of the Regulation.

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

## Product Specification

Classification according to Directive 93/42/EEC, Annex IX /

Class IIa, Rule 9

## Conformity Assessment

Procedure according to Article 11 (5) of Directive 93/42 EEC /

Declaration of conformity according to Annex VI

We declare under our sole responsibility that the products described above in the delivered version comply with the requirements of Directive 93/42/EEC.

The products are marked with the CE mark and the associated documentation is kept on the manufacturer's premises.

Notified body:

TÜV NORD Polska Sp. z o.o.

Mickiewiczza Street 29, 40-085 Katowice

Poland

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

Signature: Oliver Otte, Managing Director

# Annex 1

## SLK AIK / IPC

Risk Class: Ila

GMDN: 10969

Article-ID	Article Name	Basic UDI-DI	Article Description
3100	IPC 3	(01)4260647530568(21)3100U	3-chambers compression device
4000	Varilymph 12 Pro	(01)4260647530001(21)4000U	17 x 20 x 20 cm, digital compression therapy device

Waltrop, 13.11.2024

Place, Date



Signature: Oliver Otte, Managing Director