CE -Declaration of Conformity, DoC

Regulation (EU) MDR 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices

We as manufacture:
Levabo ApS, Sverigesvej 20A, DK-8660 Skanderborg
SRN: DK-MF-000014646

Hereby declare under our sole responsibility, as a legal manufacturer that the products specified on the products listed below, meet the general safety and performance requirements.

The products are in conformance with the provisions of the Regulations (EU) 2017/745 as amended OF THE EUROPEAN Parliament and of the council on medical devices.

The products specified on the product list below are “technical aid for positioning of patients” classified as CLASS I - medical device.
The classification is based on the requirements of Rule 1 of Annex VIII cap. III in the Regulation (EU) 2017/745. The CE marking has been affixed on the product according to Annex V of the Regulation (EU) 2017/745 and UDI according to Annex VI.

Intended use:
Prevention and treatment of pressure ulcers for bedbound patients in hospitals, nursing homes, hospices, home care and domestic use.

Product name	Product No.	Basic UDI	UDI-DI
Levaflex Twin – 90*200*14	70156	5711014LEVAFLEXT5	05711014701566
Levaflex Twin – 88*200*14	70157	5711014LEVAFLEXT5	05711014701573
Levaflex Twin – 85*200*14	70158	5711014LEVAFLEXT5	05711014701580
Levaflex Twin – 83*200*14	70159	5711014LEVAFLEXT5	05711014701597
Levaflex Basis - 90*200*14 (1 skumkerne)	70164	5711014LEVAFLEXT5	05711014701641
Levaflex Cover – 90*200*14	76139	5711014LEVAFLEXT5	05711014761393
Levaflex Cover – 85*200*14	76141	5711014LEVAFLEXT5	05711014761416

Used harmonized norms:
- DS/EN ISO 13485 medical Devices – Quality Management System
- ISO 14971
- ISO 10993 (1,5,10)
- ISO 15223-1

Skanderborg, 2025 12 18

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