

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.	GMDN	Basic UDI	UDI-DI
Heel UP Short	70001	11095	5711014HEELUPLB	05711014700019
Heel UP Medium	70007	11095	5711014HEELUPLB	05711014700071
Heel UP Long	70002	11095	5711014HEELUPLB	05711014700026
Heel UP Max	70018	11095	5711014HEELUPLB	05711014700187
Heel UP Air Medium	70036	11095	5711014HEELUPLB	05711014700369
Heel UP Cut Medium	70037	11095	5711014HEELUPLB	05711014700378
Heel UP Kids 20cm	70039	11095	5711014HEELUPLB	05711014700396
Heel UP Short +3X Inlay	70030	11095	5711014HEELUPLB	05711014700309
Heel UP Medium +3X Inlay	70031	11095	5711014HEELUPLB	05711014700316
Heel UP Long +3X Inlay	70032	11095	5711014HEELUPLB	05711014700323
Heel UP Max +3X Inlay	70033	11095	5711014HEELUPLB	05711014700330
Heel UP Fix Short	70146	11095	5711014HEELUPLB	05711014701467
Heel UP Fix Medium	70073	11095	5711014HEELUPLB	05711014700736
Heel UP Fix Long	70079	11095	5711014HEELUPLB	05711014700798
Heel UP Fix Max	70147	11095	5711014HEELUPLB	05711014701474
Heel UP Fix Short + 3X Inlay	70172	11095	5711014HEELUPLB	05711014701720
Heel UP Fix Medium +3X Inlay	70076	11095	5711014HEELUPLB	05711014700767
Heel UP Fix Long +3X Inlay	70077	11095	5711014HEELUPLB	05711014700774
Heel UP Fix Short MP	80146	11095	5711014HEELUPLB	05711014801464
Heel UP Fix Medium MP	80073	11095	5711014HEELUPLB	05711014800733
Heel UP Fix Long MP	80079	11095	5711014HEELUPLB	05711014800795
Heel UP Inlay	76015	11095	5711014HEELUPLB	05711014760150

Used harmonized norms:

- DS/EN ISO 13485 medical Devices – Quality Management System
- ISO 14971
- ISO 10993 (1,5,10)
- ISO 15223-1
- ISO 2859

Skanderborg, 2026 04 07


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