

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 with flavors included, specified on the products listed below, meet the essential health and safety requirements.

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

The classification is based on the requirements of Rule 1 of Annex VIII, if the Regulation (EU) 2017/745. The CE marking has been affixed on the product according to Annex V of the Regulation (EU) 2017/745.

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
Heel UP – Short	70001	5711014HEELUPLB	05711014700019
Heel UP – Medium	70007	5711014HEELUPLB	05711014700071
Heel UP – Long	70002	5711014HEELUPLB	05711014700026
Heel UP – Max	70018	5711014HEELUPLB	05711014700187
Heel UP – Medium +3 Inlay + Pump	70181	5711014HEELUPLB	05711014701818
Heel UP – Long + 3 Inlay + Pump	70182	5711014HEELUPLB	05711014701825
Heel UP – Short + 3 Inlay	70030	5711014HEELUPLB	05711014700309
Heel UP – Medium + 3 Inlay	70031	5711014HEELUPLB	05711014700316
Heel UP – Long + 3 Inlay	70032	5711014HEELUPLB	05711014700323
Heel UP – Max + 3 Inlay	70033	5711014HEELUPLB	05711014700330
Heel UP – Fix Short	70146	5711014HEELUPLB	05711014701467
Heel UP – Fix Medium	70073	5711014HEELUPLB	05711014700736
Heel UP – Fix Long	70079	5711014HEELUPLB	05711014700798
Heel UP – Fix Medium + 3 Inlay + Pump	70168	5711014HEELUPLB	05711014701689
Heel UP – Fix Long + 3 Inlay + Pump	70169	5711014HEELUPLB	05711014701696
Heel UP – Fix Max	70147	5711014HEELUPLB	05711014701474
Heel UP – Fix Sort + 3 Inlay	70172	5711014HEELUPLB	05711014701726
Heel UP – Fix medium + 3 Inlay	70076	5711014HEELUPLB	05711014700767
Heel UP – Fix long + 3 Inlay	70077	5711014HEELUPLB	05711014700774
Heel UP – Fix Max + 3 Inlay	70173	5711014HEELUPLB	05711014701733
Heel UP – Air Medium	70036	5711014HEELUPLB	05711014700361
Heel UP – Cut Medium	70037	5711014HEELUPLB	05711014700378
Heel UP – Kids 15 cm	70038	5711014HEELUPLB	05711014700385
Heel UP – Kids 20 cm	70039	5711014HEELUPLB	05711014700392

Used harmonized norms:

- DS/EN ISO 13485:2016 Quality Management System – Medical devices
- DS/EN ISO 9001:2008 Quality Management System
- ISO 14971
- ISO 10-993 (1,5,10)

Skanderborg, 08/02-2023


Peter Egelund, CEO

Levabo ApS
Sverigesvej 20A
8660 Skanderborg
Tel.: +45 31 70 40 25
Mail: info@levabo.dk