

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. Reusable for other patients after cleaning.

Product name	Product No.	Basic UDI	UDI-DI
All UP – Multi Small	70003	5711014ALLUPPM	05711014700033
All UP – Multi Small Soft	70105	5711014ALLUPPM	05711014700054
All UP – Multi Small + Pump	70214	5711014ALLUPPM	05711014702149
All UP – Multi Medium	70004	5711014ALLUPPM	05711014700040
All UP – Multi Large	70005	5711014ALLUPPM	05711014700057
All UP – Multi Max.	70012	5711014ALLUPPM	05711014700125
All UP – Universal	70010	5711014ALLUPPM	05711014700101
All UP – Universal Long	70015	5711014ALLUPPM	05711014700156
All UP – Universal Slim	70016	5711014ALLUPPM	05711014700163
All UP – Kidney	70014	5711014ALLUPPM	05711014700149
All UP – Head	70011	5711014ALLUPPM	05711014700118
All UP – Head Soft + Pump	70215	5711014ALLUPPM	05711014702153
All UP – Head Intubate DUO White	70103	5711014ALLUPPM	05711014701030
All UP – Head Silent & Soft	70074	5711014ALLUPPM	05711014700742
All UP – Head Kids	70040	5711014ALLUPPM	05711014700408
All UP – Head Kids Silent & Soft	70075	5711014ALLUPPM	05711014700750
All UP – Foot Sole	70080	5711014ALLUPPM	05711014700804
All UP – Wing	70006	5711014ALLUPPM	05711014700064
All UP – Arm Rest	70027	5711014ALLUPPM	05711014700279
All UP – Elbow	70028	5711014ALLUPPM	05711014700286
All UP – Elbow Medium	70048	5711014ALLUPPM	05711014700484
All UP – Elbow & Heel	70049	5711014ALLUPPM	05711014700491
All UP – Belly	70023	5711014ALLUPPM	05711014700231
All UP – Wedge 30 deg.	70024	5711014ALLUPPM	05711014700248
All UP – Multi Wedge	70053	5711014ALLUPPM	05711014700538
All UP – Lap	70025	5711014ALLUPPM	05711014700255
All UP – Lap Max	70026	5711014ALLUPPM	05711014700262
All UP – Covid 19 kit	70104	5711014ALLUPPM	05711014700047
All UP – Prone kit	70115	5711014ALLUPPM	05711014700153
All UP – Incubate Kids	70042	5711014ALLUPPM	05711014700422
All UP – Half Charlie	70213	5711014ALLUPPM	05711014702136

Used harmonized norms:

- DS/EN ISO 13485:2016 medical Devices – Quality Management System
- DS/EN ISO 9001:2015 production and control including customer care
- ISO 14971
- ISO 10-993 (1,5,10)

Skanderborg, 08/02-2023


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