

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:

Treatment of incontinence for adult patients in hospitals, nursing homes, hospices, home care and domestic use.

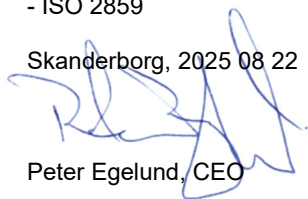
Product name	Product No.	GMDN	Basic UDI	UDI-DI
High Waist 350 ml, S	90001	35817	5711014INCONQQ	05711014900013
High Waist 350 ml, M	90002	35817	5711014INCONQQ	05711014900020
High Waist 350 ml, L	90003	35817	5711014INCONQQ	05711014900037
High Waist 350 ml, XL	90004	35817	5711014INCONQQ	05711014900044
High Waist 350 ml, XXL	90005	35817	5711014INCONQQ	05711014900051
High Waist 350 ml, XXXL	90006	35817	5711014INCONQQ	05711014900068
High Waist 90 ml, S	90011	35817	5711014INCONQQ	05711014900112
High Waist 90 ml, M	90012	35817	5711014INCONQQ	05711014900129
High Waist 90 ml, L	90013	35817	5711014INCONQQ	05711014900136
High Waist 90 ml, XL	90014	35817	5711014INCONQQ	05711014900143
High Waist 90 ml, XXL	90015	35817	5711014INCONQQ	05711014900150
High Waist 90 ml, XXXL	90016	35817	5711014INCONQQ	05711014900167
Briefs 90 ml, S	90021	35817	5711014INCONQQ	05711014900211
Briefs 90 ml, M	90022	35817	5711014INCONQQ	05711014900228
Briefs 90 ml, L	90023	35817	5711014INCONQQ	05711014900235
Briefs 90 ml, XL	90024	35817	5711014INCONQQ	05711014900242
Briefs 90 ml, XXL	90025	35817	5711014INCONQQ	05711014900259
Briefs 90 ml, XXXL	90026	35817	5711014INCONQQ	05711014900266
Boxers 450 ml, S	90031	35817	5711014INCONQQ	05711014900310
Boxers 450 ml, M	90032	35817	5711014INCONQQ	05711014900327
Boxers 450 ml, L	90033	35817	5711014INCONQQ	05711014900334
Boxers 450 ml, XL	90034	35817	5711014INCONQQ	05711014900341
Boxers 450 ml, XXL	90035	35817	5711014INCONQQ	05711014900358
Boxers 450 ml, XXXL	90036	35817	5711014INCONQQ	05711014900365
Boxers 90 ml, S	90041	35817	5711014INCONQQ	05711014900419
Boxers 90 ml, M	90042	35817	5711014INCONQQ	05711014900426
Boxers 90 ml, L	90043	35817	5711014INCONQQ	05711014900433
Boxers 90 ml, XL	90044	35817	5711014INCONQQ	05711014900440
Boxers 90 ml, XXL	90045	35817	5711014INCONQQ	05711014900457
Boxers 90 ml, XXXL	90046	35817	5711014INCONQQ	05711014900464
Boxers 200 ml, S	90051	35817	5711014INCONQQ	05711014900518
Boxers 200 ml, M	90052	35817	5711014INCONQQ	05711014900525
Boxers 200 ml, L	90053	35817	5711014INCONQQ	05711014900532
Boxers 200 ml, XL	90054	35817	5711014INCONQQ	05711014900549

Boxers 200 ml, XXL	90055	35817	5711014INCONQQ	05711014900556
Boxers 200 ml, XXXL	90056	35817	5711014INCONQQ	05711014900563

Used harmonized norms:

- DS/EN ISO 13485 medical Devices – Quality Management System
- ISO 14971
- ISO 10993 (1,5,10,23)
- ISO 15223-1
- ISO 2859

Skanderborg, 2025 08 22



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