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.

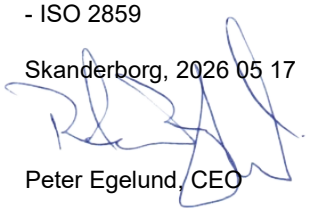
Intended use:
Treatment of incontinence for adult patients in hospitals, nursing homes, hospices, home care and domestic use.

Product name	Product No.	GMDN	Basic UDI	UDI-DI
Womans High Waist 350ml S	90001	35817	5711014INCONQQ	05711014900013
Womans High Waist 350ml M	90002	35817	5711014INCONQQ	05711014900020
Womans High Waist 350ml L	90003	35817	5711014INCONQQ	05711014900037
Womans High Waist 350ml XL	90004	35817	5711014INCONQQ	05711014900044
Womans High Waist 350ml XXL	90005	35817	5711014INCONQQ	05711014900051
Womans High Waist 350ml XXXL	90006	35817	5711014INCONQQ	05711014900068
Womans High Waist 90ml S	90011	35817	5711014INCONQQ	05711014900112
Womans High Waist 90ml M	90012	35817	5711014INCONQQ	05711014900129
Womans High Waist 90ml L	90013	35817	5711014INCONQQ	05711014900136
Womans High Waist 90ml XL	90014	35817	5711014INCONQQ	05711014900143
Womans High Waist 90ml XXL	90015	35817	5711014INCONQQ	05711014900150
Womans High Waist 90ml XXXL	90016	35817	5711014INCONQQ	05711014900167
Mens Boxers 450ml S	90031	35817	5711014INCONQQ	05711014900310
Mens Boxers 450ml M	90032	35817	5711014INCONQQ	05711014900327
Mens Boxers 450ml L	90033	35817	5711014INCONQQ	05711014900334
Mens Boxers 450ml XL	90034	35817	5711014INCONQQ	05711014900341
Mens Boxers 450ml XXL	90035	35817	5711014INCONQQ	05711014900358
Mens Boxers 450ml XXXL	90036	35817	5711014INCONQQ	05711014900365
Mens Boxers 90ml S	90041	35817	5711014INCONQQ	05711014900419
Mens Boxers 90ml M	90042	35817	5711014INCONQQ	05711014900426
Mens Boxers 90ml L	90043	35817	5711014INCONQQ	05711014900433
Mens Boxers 90ml XL	90044	35817	5711014INCONQQ	05711014900440
Mens Boxers 90ml XXL	90045	35817	5711014INCONQQ	05711014900457
Mens Boxers 90ml XXXL	90046	35817	5711014INCONQQ	05711014900464
Mens Boxers 200ml S	90051	35817	5711014INCONQQ	05711014900518
Mens Boxers 200ml M	90052	35817	5711014INCONQQ	05711014900525
Mens Boxers 200ml L	90053	35817	5711014INCONQQ	05711014900532
Mens Boxers 200ml XL	90054	35817	5711014INCONQQ	05711014900549
Mens Boxers 200ml XXL	90055	35817	5711014INCONQQ	05711014900556
Mens Boxers 200ml XXXL	90056	35817	5711014INCONQQ	05711014900563
Womans High Waist 350ml Buttons S	90063	35817	5711014INCONQQ	05711014900631
Womans High Waist 350ml Buttons M	90064	35817	5711014INCONQQ	05711014900648

Womans High Waist 350ml Buttons L	90065	35817	5711014INCONQQ	05711014900655
Womans High Waist 350ml Buttons XL	90066	35817	5711014INCONQQ	05711014900662
Womans High Waist 350ml Buttons XXL	90067	35817	5711014INCONQQ	05711014900679
Womans High Waist 350ml Buttons XXXL	90068	35817	5711014INCONQQ	05711014900686
Mens Boxers 450ml Buttons S	90075	35817	5711014INCONQQ	05711014900754
Mens Boxers 450ml Buttons M	90076	35817	5711014INCONQQ	05711014900761
Mens Boxers 450ml Buttons L	90077	35817	5711014INCONQQ	05711014900778
Mens Boxers 450ml Buttons XL	90078	35817	5711014INCONQQ	05711014900785
Mens Boxers 450ml Buttons XXL	90079	35817	5711014INCONQQ	05711014900792
Mens Boxers 450ml Buttons XXXL	90080	35817	5711014INCONQQ	05711014900808
Womans Boxers 200ml S	90087	35817	5711014INCONQQ	05711014900877
Womans Boxers 200ml M	90088	35817	5711014INCONQQ	05711014900884
Womans Boxers 200ml L	90089	35817	5711014INCONQQ	05711014900891
Womans Boxers 200ml XL	90090	35817	5711014INCONQQ	05711014900907
Womans Boxers 200ml XXL	90091	35817	5711014INCONQQ	05711014900914
Womans Boxers 200ml XXXL	90092	35817	5711014INCONQQ	05711014900921
Womans High Waist 350ml S	90093	35817	5711014INCONQQ	05711014900938
Womans High Waist 350ml M	90094	35817	5711014INCONQQ	05711014900945
Womans High Waist 350ml L	90095	35817	5711014INCONQQ	05711014900952
Womans High Waist 350ml XL	90096	35817	5711014INCONQQ	05711014900969
Womans High Waist 350ml XXL	90097	35817	5711014INCONQQ	05711014900976
Womans High Waist 350ml XXXL	90098	35817	5711014INCONQQ	05711014900983

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, 2026 05 17



Peter Egelund, CEO