

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
All Up – Multi Small	70003	41058	5711014ALLUPPM	05711014700033
All Up – Universal	70010	41058	5711014ALLUPPM	05711014700101
All Up – Kidney	70014	41058	5711014ALLUPPM	05711014700149
All Up – Head	70011	41058	5711014ALLUPPM	05711014700118
All Up – Wing	70006	41058	5711014ALLUPPM	05711014700064
All Up – Arm Rest	70027	41058	5711014ALLUPPM	05711014700279
All Up – Elbow & Heel	70049	41058	5711014ALLUPPM	05711014700491
All Up – Wedge 30 deg.	70024	41058	5711014ALLUPPM	05711014700248
All Up – Half Charlie	70213	41058	5711014ALLUPPM	05711014702136
All Up – Mini Bib	76014	41058	5711014ALLUPPM	05711014760143
All Up – Halv Charlie Cover	76140	41058	5711014ALLUPPM	05711014761409
All Up – Foot sole MP	80080	41058	5711014ALLUPPM	05711014800801
All Up – Halv Charlie MP	80213	41058	5711014ALLUPPM	05711014802133

Used harmonized norms:

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

Skanderborg, 2025 03 01

Peter Egelund, CEO