

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
Turn All leva Flex System 3CT	70161	17593	5711014TURNALLLB	05711014701610
Turn All System 1CT	70112	17593	5711014TURNALLLB	05711014701122
Turn All System 3CT	70128	17593	5711014TURNALLLB	05711014701283
Turn All System 3CT Bariatric	70098	17593	5711014TURNALLLB	05711014700989
Turn All Cover TPU	70114	17593	5711014TURNALLLB	05711014701146
Turn All Bariatric Cover TPU	70126	17593	5711014TURNALLLB	05711014701269
Turn All Mattres	70082	17593	5711014TURNALLLB	05711014700828
Turn All Bariatric Mattress	70124	17593	5711014TURNALLLB	05711014701245
Turn All Adapter 15/30 dg. tilt	76167	17593	5711014TURNALLLB	05711014761676
Turn all Adapt.doub.side tilt/hug all cycls	76168	17593	5711014TURNALLLB	05711014761683
Turn All Adapter singl side tilt L/R + st.hug	76210	17593	5711014TURNALLLB	05711014762109
Turn All System 1CT 30 CR	70225	17593	5711014TURNALLLB	05711014702259
Turn All System 3CT CR	70226	17593	5711014TURNALLLB	05711014702266

Used harmonized norms:

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

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