Thesis Technology

LimbO®
The original waterproof protector

EU Declaration of Conformity

CE

Medical Devices Regulation (MDR) 2017/745 as transposed into European national law by the member states:

Thesis Technology Products Ltd hereby declares that this device is in conformity with the General Safety and Performance (GSPR) requirements (annex I) and provisions of the Medical Devices Regulation (MDR) 2017/745 that apply and the CE Mark may be affixed. This declaration of conformity is issued under sole responsibility of the manufacturer.

General Product Name:	**LimbO Waterproof Protectors**
Legal Manufacturer: (Name on Label)	Thesis Technology Products Ltd, Brooks Green Farm, Brooks Lane, Bosham, Chichester, West Sussex, PO18 8JX, UK
SRN:	TBC
Basic UDI-DI:	506003204
Variants:	As per Appendix II (this document) – Product Listing/Schedule
Intended Use:	To protect casts, bandages, dressings and PICC/ mid lines from water in the shower or bath.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta.
Medical Device Regulation Assessment Route:	Self-certification by Medical Device Regulation MDR 2017/745 annex IV; EC Declaration of Conformity; Registration of persons responsible for placing devices on the market.

Name: Ana Palmer

Position: Managing Director

Signed: Ana Palmer

Date: 25th March 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
MDR 2017/745	Device Risk Classification as per Annex VIII
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name
M100	Adult Full Leg
M100S	Adult Full Leg - Short
M100L	Adult Full Leg - Long
M80LL	Adult Full Leg - Slim
M200FL	Adult Full Leg - Extra heavy leg
AB80	Airboot Model
M80/MP80	Adult 1/2 Leg
M80S/MP80S	Adult 1/2 Leg - Short
M80L	Adult 1/2 Leg - Long
M76/ MP76	Adult 1/2 Leg - Slim
M76S	Adult 1/2 Leg - Slim - Short
M76L	Adult 1/2 Leg – Slim - Long
M180/ MP180	Adult 1/2 Leg - Large
M180S/ MP180S	Adult 1/2 Leg - Large - Short
M180L	Adult 1/2 Leg - Large - Long
M200HL	Adult 1/2 Leg - Extra heavy leg
FL 3	Child Small Full Leg - 3 years
FL 45	Child Full Leg 4 - 5 years
FL 67	Child Full Leg 6-7 years
FL 810	Child Full Leg 8-10 years
FL1113	Full Leg 11-13 years
BK 810	Child 1/2 Leg 8 - 10 years
BK 1113	1/2 Leg 11 - 13 years
M60L	Adult Full Arm - Slim
M70	Adult Full Arm
M87	Adult Full Arm - Large

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FA23	Child Arm 2 -3 years
FA 45	Child Full Arm 4 - 5 years
FA 67	Child Full Arm 6 - 7 years
FA 810	Child Full Arm 8 - 10 years
FA 1113	Full Arm 11 - 13 years
M60	Adult 1/2 Arm – Slim - Medium
M67	Adult 1/2 Arm - Medium - Large
MITT	Adult Hand
BE 810-40	Child 8-10 years 1/2 Arm - Slim
BE 810-50	Child 8-10 years 1/2 Arm - Standard
BE 1113-40	Child 11-13 years 1/2 Arm - Slim
BE 1113-50	Child 11-13 years 1/2 Arm - Standard
M86	Adult Knee
M65/ MP65	Adult Elbow
M75/MP75	Adult Medium
M85	Adult Elbow Large
M45	Child Elbow
M45S	Child Elbow Small
M20	Adult Foot Small
M25	Adult Foot Medium to Large

Version History

Version	Compiled by	Date	Description
1.1	Andrea Coleman	25/03/2021	First issue