Thesis Technology

LimbO®
The original waterproof protector

EU Declaration of Conformity

CE

Thesis Technology Products Ltd declares that under our sole responsibility, the product **LimbO Waterproof Protector** is in conformity with the General Safety and Performance (GSPR) requirements of the following EC Regulations:(annex I) and provisions of the Medical Devices Regulation (MDR) 2017/745 that apply and the CE Mark may be affixed.

General product name:	**LimbO Waterproof Protectors**
Legal manufacturer:	Thesis Technology Products Ltd, Brooks Green Farm, Brooks Lane, Bosham, Chichester, West Sussex, PO18 8JX, UK
SRN:	GB-MF-000009862
Basic UDI-DI:	506003204
GMDN code:	64560
Variants:	As per Appendix I (below) – Product Listing
Intended use:	To protect casts, bandages, dressings and PICC/ mid lines from water in the shower or bath.
Medical device classification:	Class I (rule I)
Notified body:	Not Applicable for Class I self-declaration devices
EU authorised representative:	European Healthcare & Device Solutions (Ireland) Ltd. Stratton House, Bishopstown Road, Bishopstown, Cork, Ireland.
Authorised rep SRN:	IE-AR-000003999
Conformity assessment route:	Self-classification according to Annex I, II, III and Annex IV (Declaration of Conformity) of Regulation MDR 2017/745 (Medical Device Regulation)
Applicable standards (applied in full):	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

Name: Ana Palmer

Position: Managing Director

Signature: Ana Palmer

Date: 11th November 2024

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Appendix I – Product Listing

Catalogue Number	Description/Name
M100/ MP100	Adult Full Leg
M100S/ MP100S	Adult Full Leg - Short
M100L/ MP100L	Adult Full Leg - Long
M80LL/MP80LL	Adult Full Leg - Slim
M200FL/ MP200FL	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/MP76S	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/ MP200HL	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/MP60L	Adult Full Arm - Slim
M70/MP70	Adult Full Arm
M87/MP87	Adult Full Arm - Large
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 – Slim to Medium
M75/MP75	Adult Elbow – Medium to Large
M85/MP85	Adult Elbow – Extra Large
M45/MP45	Adult Elbow – Extra Slim
M45S	Child Elbow Short
M20/ MP20	Adult Foot Small
M25/ MP25	Adult Foot Medium to Large