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
Signature: Ana Palmer

Position: Managing Director
Date: 15th July 2021