

Declaration of Conformity

for Thermoskin

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

UPI declares under their sole responsibility that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	Thermoskin
Legal Manufacturer: (Name on Label)	<u>United Pacific Industries Pty Ltd</u> 10 Eastspur Court Kilsyth Victoria VIC 3137 Australia
SRN:	AU-MF-000002766
Basic UDI-DI:	609580TSKN826718B
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Management of musculoskeletal injuries through compression, support, and heat generation.
MDR Classification:	Class I
Notified Body:	Not applicable for Class I medical devices.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing the EU declaration of Conformity in accordance with Article 19 after drawing up the technical documentation set out in Annexes II and III.

Name Matthew Symington

Position Chief Executive Officer

Signed



Date 26/11/2021

Place

Melbourne, Australia

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.

Appendix I – Applicable Standards

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

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
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 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part / Catalogue Number	Name	GMDN Code
8*100	Thermoskin CMC Thumb Support - Left	41455
8*101	Thermoskin CMC Thumb Support - Right	41455
8*192	Thermoskin Thermal Gloves (pair)	41455
8*199	Thermoskin Thermal Gloves (pair)	41455
8*638	Thermoskin CMC Flexion Thumb Brace - Left	41455
8*639	Thermoskin CMC Flexion Thumb Brace – Right	41455
8*190	Thermoskin Thermal Thumb Support	41455
8*214	Thermoskin Thermal Wrist Hand Support - Left	41455
8*215	Thermoskin Thermal Wrist Hand Support - Right	41455
8*216	Thermoskin Thermal Wrist Support	41455
8*226	Thermoskin Universal Wrist Wrap Support	41455
80141	Thermoskin Shoulder Stabiliser	41455
80171	Thermoskin Adjustable Thumb Brace	41455
80172	Thermoskin Exo Adjustable Thumb Stabiliser	41455
80180	Thermoskin Adjustable Wrist Brace Left	41455
80181	Thermoskin Adjustable Wrist Brace Right	41455
80626	Thermoskin Compression Wrist Wrap	41455
80630	Thermoskin Soft Cervical Collar	41039
80631	Thermoskin Arm Sling	13622
80634	Thermoskin Abdominal Binder	33031
80707	Thermoskin Sports Calf/Shin Adjustable	41455
80711	Thermoskin Sports Thigh/Hamstring Adjustable	41455
80791	Thermoskin Sports Wrist Adjustable	41455
80792	Thermoskin Sports Ankle Adjustable	41472
80798	Thermoskin Sports Tennis Elbow Adjustable	41455
8*112	Thermoskin SI Belt	33031
8*132	Thermoskin Walk On Circulation Slippers	41472
8*203	Thermoskin Thermal Adjustable Ankle Wrap	41472
80103	Thermoskin Exo Adjustable Ankle Wrap	41472
8*204	Thermoskin Thermal Ankle Support	41472

Part / Catalogue Number	Name	GMDN Code
8*205	Thermoskin Adjustable Tennis Elbow Strap	41455
80105	Thermoskin Exo Adjustable Tennis Elbow Strap	41455
8*207	Thermoskin Thermal Calf Support	41472
8*208	Thermoskin Thermal Knee Support	41472
8*209	Thermoskin Thermal Knee Patella Support	41472
8*110	Thermoskin Exo Knee Stabiliser	41472
8*211	Thermoskin Thermal Thigh/Hamstring	41472
8*213	Thermoskin Thermal Adjustable Back Support	33031
8*217	Thermoskin Thermal Elbow Support	41455
80117	Thermoskin Exo Adjustable Elbow Support	41455
8*120	Thermoskin Exo Double Shoulder Support	41455
8*221	Thermoskin Thermal Adjustable Neck Wrap	41039
8*222	Thermoskin Thermal Groin Hip - Left	41472
8*223	Thermoskin Thermal Groin Hip - Right	41472
8*225	Thermoskin Thermal Shorts	41472
8*227	Thermoskin Thermal Adjustable Lumbar Support	33031
8*232	Thermoskin Thermal AFG	41472
8*234	Thermoskin Thermal Plantar FXT Night Support	41472
8*238	Thermoskin Thermal Wrist Hand Brace with Thumb Splint Left	41455
8*239	Thermoskin Thermal Wrist Hand Brace with Thumb Splint Right	41455
80138	Thermoskin Thermal Wrist Hand Brace with Thumb Splint Left	41455
80139	Thermoskin Thermal Wrist Hand Brace with Thumb Splint Right	41455
8*240	Thermoskin Thermal Adjustable Shoulder Stabiliser	41455
8*247	Thermoskin Thermal Knee Derotation Brace	41472
8*246	Thermoskin Thermal Knee Stabiliser	41472
8*257	Thermoskin Thermal Thumb Spica Left	41455
8*258	Thermoskin Thermal Thumb Spica Right	41455
80261	Thermoskin Adjustable Patella Tendon Strap	41472
80161	Thermoskin Exo Adjustable Patella Tendon Strap	41472
8*263	Thermoskin Thermal Mouldable Thumb Splint -Left	41455
8*264	Thermoskin Thermal Mouldable Thumb Splint Right	41455
8*266	Thermoskin Thermal Patella Tracking Stabiliser	41472
8*268	Thermoskin Thermal Dual Stabilising Wrist Brace Left	41455
8*269	Thermoskin Thermal Dual Stabilising Wrist Brace Right	41455
8*271	Thermoskin Thermal Thumb Stabiliser	41455
8*276	Thermoskin Thermal Knee Brace Open - Single Pivot Hinge	41472
8*277	Thermoskin Thermal Knee Brace Open - Dual Pivot Hinge	41472
8*278	Thermoskin Thermal Knee Brace Open - Range of Motion Hinge	41472
8*249	Thermoskin Thermal Knee Brace - Single Pivot Hinge	41472
8*265	Thermoskin Thermal Knee Brace - Flexion/Extension Hinge	41472
8*274	Thermoskin Thermal Knee Brace - Dual Pivot Hinge	41472
8*275	Thermoskin Thermal Knee Brace - Range of Motion Hinge	41472
8*280	Thermoskin Thermal Wrist Brace Left	41455
8*281	Thermoskin Thermal Wrist Brace Right	41455
8*284	Thermoskin Thermal Adjustable Knee Wrap Stabiliser	41472

Part / Catalogue Number	Name	GMDN Code
8*285	Thermoskin Thermal Knee Brace Open - Flexion/Extension Hinge	41472
8*302	Thermoskin Thermal Adjustable Knee Support Universal	41472
8*300	Thermoskin Thermal Adjustable Knee Support - Left	41472
8*301	Thermoskin Thermal Adjustable Knee Support - Right	41472
8*306	Thermoskin Thermal Elbow Wrap	41455
8*601	Thermoskin Walk On FXT Ankle Compression Socks	45606
8*602	Thermoskin Walk On FXT Calf Compression Socks	45606
8*603	Thermoskin Walk On FXT Crew Compression Socks	45606
8*604	Thermoskin Compression Ankle Sleeve	41472
8*605	Thermoskin Compression Adjustable Figure 8 Ankle Wrap	41472
8*608	Thermoskin Compression Knee Sleeve	41472
8*609	Thermoskin 4-Way Compression Knee Sleeve	41472
8*611	Thermoskin Dynamic Compression Knee Sleeve	41472
8*612	Thermoskin Dynamic Compression Ankle Sleeve	41472
8*613	Thermoskin Dynamic Compression Elbow Sleeve	41472
8*617	Thermoskin Compression Elbow Sleeve	41455
80622	Thermoskin Compression Multi-Purpose Wrap	41455
8*627	Thermoskin Adjustable Back Stabiliser	33031
8*629	Thermoskin Hernia Belt	47218
8*632	Thermoskin Clavicle Support	41455
8*633	Thermoskin Plaster Shoe	41472
80642	Thermoskin Wrist Brace Left Black	41455
80643	Thermoskin Wrist Brace Right Black	41455
8*646	Thermoskin Compression Stabilising Knee Sleeve	41472
8*649	Thermoskin Dynamic Compression Knee Stabiliser	41472
8*660	Thermoskin Ankle Armour Brace	41472
8*661	Thermoskin Ankle Defence Brace	41472
8*677	Thermoskin OL Knee Brace - Left	41472
8*678	Thermoskin OL Knee Brace - Right	41472
8*790	Thermoskin Sports Ankle Brace	41472
8*793	Thermoskin Sports Knee Stabiliser Adjustable	41472
8*794	Thermoskin Sports Knee Adjustable	41472
8*796	Thermoskin Sports Thumb Adjustable - Left	41455
8*797	Thermoskin Sports Thumb Adjustable - Right	41455
80115	Thermoskin Exo Adjustable Wrist Support	41455
80113	Thermoskin Exo Adjustable Stabilising Back Support	33031

Version History

Version	Compiled by	Date	Description
1.0	Matthew Symington	26/03/2021	First issue under the MDR.
2.0	Matthew Symington	13/04/2021	Update with SRN
3.0	Matthew Symington	15/06/2021	Update with new products
4.0	Matthew Symington	26/11/2021	Update wording