

Declaration of Conformity

for the Koolpak Reusable Hot and Cold Packs

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

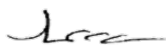
The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Koolpak Reusable Hot and Cold Packs
Legal Manufacturer: (Name on Label)	CMUK Visual Safety Ltd, also trading as Koolpak Ltd
Manufacturers SRN:	GB-MF-000002744
Basic UDI-DI:	5026448Hot&ColdUH
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	1 st Floor, Fleetsbridge House, Fleets Corner Business Park, Poole, Dorset, BH17 0LA, UK.
MDR Classification:	Class I
Notified Body:	NB
EC Certificate:	GB19/964249
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 of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Jason Loader

Position Compliance Manager

Signed



Date

23 Jan 2025

Place

Poole, UK

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 ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
ISO 10993-1:2018	Biological evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
ISO10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Evaluation for <i>In vitro</i> cytotoxicity
ISO 10993-10:2021	Biological Evaluation of Medical Devices – Part 10: Tests for skin sensitizations
EN62366-1:2015/AMD:2020	Medical Devices – Part 1: Application of usability engineering to medical devices

Appendix II – Product Listing/Schedule

Catalogue Number		UDI-DI	Device Name	EMDN Code
Eureka	Koolpak			
CP04	HCS80	15026448000152	Reusable Hot and Cold Pack – 13x14cm	M9001 – Cryotherapy and Thermotherapy Devices
CP02	HCM30	15026448000114	Reusable Hot and Cold Pack – 12x29cm	
CP05	HCL30	15026448000176	Reusable Hot and Cold Pack – 16x28cm	
DRCP2	LHCS80	15026448000299	Luxury Reusable Hot and Cold Pack – 13x14cm	
DRCP1	LHCM30	15026448000138	Luxury Reusable Hot and Cold Pack – 12x29cm	
PHYSIO	HCYP8	15026448000800	Physio Reusable Hot and Cold Pack – 36x28cm	
LXPHYSIO	LHCPY6	15026448000817	Luxury Physio Reusable Hot and Cold Pack – 36x28cm	
ELEP01	ELL80	15026448000206	Elly the Elephant Hot and Cold Gel Pack -	
WPPD01	WOO80	15026448000190	Woopsadaisy Hot and Cold Gel Pack	
RLHCM	RLHCM24	15026448000077	Koolpak Reusable Hot and Cold Pack and Elasticated Holster	
AEC6113	LHCSTR18	15026448000992	Koolpak Reusable Hot and Cold Pack with Elasticated Strap and Cover	
n/a	LHCRD60	15026448004853	Round Hot and Cold Pack	
n/a	LHCOV30	15026448004877	Oval Hot and Cold Pack	
AEC8276	HCGSS	15026448004914	Hot and Cold Gel Sleeve (Small)	
AEC8277	HCGSM	15026448004938	Hot and Cold Gel Sleeve (Medium)	
AEC8276	HCGSL	15026448004952	Hot and Cold Gel Sleeve (Large)	
AEC8334	FLCPM	15026448004976	Flexible Cold Gel Pack (Medium)	
AEC8335	FLCPL	15026448004983	Flexible Cold Gel Pack (Large)	
AEC8336	FLCPXL	15026448004990	Flexible Cold Gel Pack (X-Large)	
AEC8337	FLCPN	15026448005003	Flexible Cold Gel Pack (Neck)	
AEC8338	HCNECK	15026448005010	Hot and Cold Pack (Neck)	
AEC8339	HCBACK	15026448005027	Hot and Cold Pack (Back)	
AEC8340	HCBKN	15026448005034	Hot and Cold Pack (Back with Neoprene Wrap)	
AEC8341	HCHDN	15026448005041	Hot and Cold Pack (Head with Neoprene Wrap)	
N/A	MHPS48	15026448000985	Reusable Moist Heat Pack – 15x15cm	
AEC1765	MHPM36	15026448001029	Reusable Moist Heat Pack – 12x29cm	
AEC8595	HCGC18	15026448005201	Hot & Cold Gel Cap - 15 x 38cm	
AEC9172	RLHCMF24	15026448005393	Hot & Cold Gel Pack with Elasticated Compression Wrap and Cover	
AEC9173	MHWR12	15026448005416	Moist Heat Wrap - 13 x 45cm	
AEC9380	HCGSH14	15026448005447	Hot & Cold Gel Sleeve - Shoulder - 41 x 33cm	
AEC9381	HCANK30	15026448005454	Hot & Cold Pack - Ankle - 17.5 x 32cm	
AEC9382	HCKNE12	15026448005461	Hot & Cold Pack - Knee - 26 x 55cm	
AEC9383	HCSHLD8	15026448005478	Hot & Cold Pack - Shoulder - 26 x 24cm	
AEC9384	HCBRST20	15026448005485	Hot & Cold Pack - Breast - 18 x 21cm - Pk 2	
AEC9385	HCWRST30	15026448005546	Hot & Cold Pack - Wrist - 10 x 51cm	
AEC9792	COLDRP36	15026448005614	Cold Recovery Pack - 89 x 11.5cm	

Version History

Version	Compiled by	Date	Description
1.0	Kelly Lyon	22 Jan 2024	New Issue

2.0	Wilhemina D'Costa	23 Jan 2025	Change of compliance manager and addition of new products
-----	-------------------	-------------	---