CE Declaration of Conformity

According Medical Device Regulation (EU) 2017/745

Declaration Number	DC - 2021 -2	
Manufacturer	Interweave Textiles Ltd. Interweave House, Unit 1A, Lowfields Business Park, Old Power Way, Elland, West Yorkshire HX5 9DE. Registered No. 05267141 England. A wholly owned subsidiary of John Horsfall & Sons (Greetland) Limited. Registered Office: Birkby Grange, Birkby Hall Road, Huddersfield, West Yorkshire HD2 2XB	
Product Name	THERMARMOUR® & THERMARMOUR® Extreme Product Range	
Product Codes	ORV+WR10N+01 ORV+WR10N+06 ORV+WR10N+07 ORV+WR10N+08 ORV+WR10N+09 OB000100150---G&WM50 OB000150200---OVEM50 OB201-86192---HVGM53 OB201-86192---OVEM53 OB203-86137---OVEM53 OB000150200---G&WM50 OB602236150---OVEM52 OB200-97-86SMLOVEM50 OB200100137---OVEM50 OB000150200---G&WM55 OB000100150---G&WM55 OB220LGE--G&WM55 OB202-55-57---G&WM55 OB210LGE ---G&WM55 OB620LG----G&WM55 OB610-25-33---G&WM55	ORV+WR10N+18 ORV+WR10N+20 ORV+WR10N+23 ORV+WR10N+24 CAR+WR10N+02 CAR+WR10N+03 CAR+WR10N+04 CAR+WR10N+06 CAR+WR10N+08 CAR+WR10N+09 ORV+WR10N+11 ORV+WR10N+12 ORV+WR10N+13 ORV+WR10N+14 ORV+WR10N+15
Product Description	A range of products manufactured out of the ORVECARE's proprietary Thermarmour® & Thermarmour® Extreme material. All products in the range are passive warming Class 1 Medical Devices.	
Intended Use	Passive warming products to keep and maintain patients at a normothermic level in emergency and clinical settings.	
Basis UDI-DI	506088527THERMF8	
Single Registration Number	Not yet available	
Branding	THERMARMOUR® THERMARMOUR® Extreme	
Classification	MDR, Annex VIII	
Rule Number	Class I, Annex VIII, Rule Number 1	
EU-REP	Obelis Group, Boulevard Brand Whitlock 30, Brussels 1200, Belgium +32 (0]2 732 59 54 | sales@obelis.net, www.obelis.net	

Declaration
Interweave Textiles Ltd. hereby declares that the device specified above conforms with the Annex 1 - Essential Requirements of the Medical Device Regulations - (EU) 2017/745 of April 5, 2017.

The stated products are manufactured by Interweave Textiles Ltd in accordance with the scope of a quality system which meets the requirements of the Medical Device Regulations - (EU) 2017/745 of April 5, 2017.

All relevant documents are held within the technical file. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Elland, 12th June 2025

Place, Date

Legally binding signature, Function
C H Benson General
Manager Interweave Textiles Ltd.