

DECLARATION OF CONFORMITY

We

DAN-FOAM ApS
Holmelund 43, DK-5560 Aarup

declare under our sole responsibility that the

TEMPUR® Pressure Redistributing Products,

described in the enclosed paper (page 2) to which this declaration relates, are in conformity with the following harmonised standards or other normative documents:

National Standard reference	Title
DS/EN 1041	Information supplied by the manufacturer with medical devices
DS/EN 12182	Technical aids for disabled persons – General requirements and test methods
DS/EN/ISO 14971	Medical devices – Application of risk management to medical devices

following to the provisions of 93/42/EEC and 2007/47/EC Directives (Medical Devices Class 1).

Aarup 13th February 2017



Kasper Sørensen, Managing Director

Category	Commercial Product Name	TEMPUR-MED®	TEMPUR®
Mattresses	MED Mattress (all models)	X	
	Original 15, 19, 20, 21 and 25		X
	Original 15 XXL		X (phase out 10/4/2017)
	Original Deluxe 17 and 22		X (Only velour covers)
Toppers	Topper 7	X	X (Only velour + 2side covers)
	Topper 3.5		X (Only Velour covers)
	Topper Deluxe 3.5		X
	Topper Scanner 4, 5 and 7	X	
	Travel Set		X
Pillows	Original Pillow (incl. Travel)	X	X
	Millennium Pillow	X	X
	Classic Pillow	X	X
	Comfort Pillow (incl. travel)		X (Only Velour covers)
Cushions	Wheelchair Cushion (all models)	X	X
	Doughnut Cushion	X	
	Seat Cushion	X	
	Seat Wedge	X	
	Transit Lumbar Support	X	X
	Lumbar Support	X	X
Positioning Products	Universal Pillow	X	X
	Positioning Roll	X	
	Multi Pillow	X	X
	Multi Positioning Pillow	X	
	Bed Back Support	X	X
	Lateral Support	X	
	Leg Spacer (all models)	X	X (Only if FR treated)
	Vein Cushion	X	
	Bed Wedge	X	
	Floating Heel Cushion	X	
	Head Support	X	
	Transit Pillow	X	X
	Long Hug Pillow		X
Operating Products	Operating Table Pad	X	
	Operating Arm Pad	X	
	Lateral Positioning Kit incl. Extension	X	
	Prone Positioning Kit	X	
	Intubation Pillow	X	
	Operating Support Neck Pillow	X	
	Arm/Leg Support	X	
	Leg Support	X	
Dental Products	Dental Pillow	X	
	Ergonomic Dental Pillow	X	
	Dental Pad	X	