

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Therafin Corp.	9450 W Laraway Road, Frankfort, IL 60423 USA	

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
MedEnvoy Global B.V.	PrinsesMargrietplantsoen 33 Suite 123 2595 AM The Hague The Netherlands	NL-AR- 000024028	+31 70 326 21 48 EU-AR@medenvoyglobal.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
Multi-Axis Headrest Bracket and SureLock Headrest Bracket	See Listing
Intended Purpose	Basic UDI-DI
To provide posterior head support.	See Listing

RISK CLASS FOR DEVICES		
Device Classification	Common Specifications / Standards	
Class: I	ISO 16840-3	
Rule: 1		

Therafin Corp. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Peter Cionitti

TITLE: Director Product Management

SIGNATURE:



PLACE: Frankfort, IL USA

DATE: 1/23/2024

Product Listing:

<u>Catalog Number</u>	<u>Product Name</u>	<u>Basic UDI</u>	<u>UDI-DI (GTIN) with date</u>
50215	HEADREST HARDWARE, MULTI-AXIS OFFSET.	0840252950215B2	00840252901089
50215TOP	HEADREST HARDWARE, MULTI-AXIS OFFSET, ITOP	0840252950215TOPPR	00840252902277
50215ASL	HEADREST HARDWARE, MULTI-AXIS OFFSET, ASL	0840252950215ASLAJ	00840252924118
32975	HEADREST HARDWARE, HORIZONTAL SLIDE MOUNT	0840252932975CF	00840252900822
34189	HEADREST HARDWARE, MULTI-AXIS OFFSET, ASL W/SHORTENED OFFSET BAR	0840252934189UM	00840252951992
32967	HEADREST MOUNTING BRACKET, EXTRUDED WITH LEVER	0840252932967V5	00840252915512
50218	HEADREST HARDWARE, SURELOCK MULTI-AXIS.	0840252950218TV	00840252901096
50218TOP	HEADREST HARDWARE, SURELOCK MULTI-AXIS, ITOP	0840252902284	00840252902284