

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 2148 EU-AR@medenvoyglobal.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
ProFit Soft and ProfitAdjust Headrest Pads	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: 9/6/2023

Product Listing (next page)

<u>Catalog Number</u>	<u>Product Name</u>	<u>Basic UDI</u>	<u>UDI-DI (GTIN)</u>
50365	HEADREST PAD, PRO-FIT 5X8" SOFT WITH SMOOTH COVER, SMALL.	0840252950365UB	00840252901232
50366	HEADREST PAD, PRO-FIT 5X10" SOFT WITH SMOOTH COVER, MEDIUM.	0840252950366UD	00840252901249
50367	HEADREST PAD, PRO-FIT 5X14" SOFT WITH SMOOTH COVER, LARGE.	0840252950367UF	00840252901256
50374	HEADREST PAD, PRO-FIT 5X8" SOFT WITH KNIT COVER, SMALL.	0840252950374UC	00840252901317
50375	HEADREST PAD, PRO-FIT 5X10" SOFT WITH KNIT COVER, MEDIUM.	0840252950375UE	00840252901324
50376	HEADREST PAD, PRO-FIT 5X14" SOFT WITH KNIT COVER, LARGE.	0840252950376UG	00840252901331
50365TOP	HEADREST PAD, PRO-FIT 5X8" SOFT WITH SMOOTH COVER, SMALL, ITOP	0840252950365TOPFH	00840252902321
50366TOP	HEADREST PAD, PRO-FIT 5X10" SOFT WITH SMOOTH COVER, MEDIUM, ITOP	0840252950366TOPFQ	00840252902338
50367TOP	HEADREST PAD, PRO-FIT 5X14" SOFT WITH SMOOTH COVER, LARGE, ITOP	0840252950367TOPFX	00840252902345
50346	HEADREST COVER, FOR PRO-FIT 5X8" SOFT PAD, KNIT SMALL	0840252950346U7	00840252925061
50347	HEADREST COVER, FOR PRO-FIT 5X10" SOFT PAD, KNIT MEDIUM	0840252950347U9	00840252925078
50348	HEADREST COVER, FOR PRO-FIT 5X14" SOFT PAD, KNIT LARGE	0840252950348UB	00840252901195
50351	HEADREST COVER, FOR PRO-FIT 5X8" SOFT PAD, SMOOTH SMALL	0840252950351TY	00840252925108
50352	HEADREST COVER, FOR PRO-FIT 5X10" SOFT PAD, SMOOTH MEDIUM	0840252950352U2	00840252925115
50353	HEADREST COVER, FOR PRO-FIT 5X14" SOFT PAD, SMOOTH LARGE	0840252950353U4	00840252925122
50370	HEADREST COVER, FOR PRO-FIT ADJUSTABLE PAD, SMOOTH LARGE.	0840252950370U4	00840252901287
50371	HEADREST COVER, FOR PRO-FIT ADJUSTABLE PAD, KNIT SMALL	0840252950371U6	00840252901294
50372	HEADREST COVER, FOR PRO-FIT ADJUSTABLE PAD, KNIT LARGE	0840252950372U8	00840252901300
34183	HEADREST PAD, PRO-FIT 5X10" SOFT PAD W/SMOOTH COVER, MEDIUM ROHO	0840252934183U9	00840252917783
34184	HEADREST PAD, PRO-FIT 5X14" SOFT PAD W/ SMOOTH COVER, LARGE ROHO	0840252934184UB	00840252917790
50361	HEADREST PAD, PRO-FIT ADJUSTABLE WITH KNIT COVER, LARGE.	0840252950361U3	00840252901218
50363	HEADREST PAD, PRO-FIT ADJUSTABLE WITH KNIT COVER, SMALL.	0840252950363U7	00840252901225
50368	HEADREST PAD, PRO-FIT ADJUSTABLE WITH SMOOTH COVER, SMALL.	0840252950368UH	00840252901263
50368TOP	HEADREST PAD, PRO-FIT ADJUSTABLE WITH SMOOTH COVER, SMALL, ITOP	0840252950368TOPG6	00840252902352
50369	HEADREST PAD, PRO-FIT ADJUSTABLE WITH SMOOTH COVER, LARGE.	0840252950369UK	00840252901270
50369TOP	HEADREST PAD, PRO-FIT ADJUSTABLE WITH SMOOTH COVER, LARGE, ITOP	0840252950369TOPGD	00840252902369