



DICHIARAZIONE DI CONFORMITÀ UE / EU DECLARATION OF CONFORMITY

Date, June 27th 2026

Fabbricante / Manufacturer: ESSEBI MEDICAL SRL dba TOTIM®

Indirizzo / Address: Strada Campo del Fiume 84

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Dispositivo Medico / Medical Device: TOTIM® Patient Cushion Positioning System

SRN (Single Registration Number): SM-MF- 000056722

Identificazione del dispositivo / Identification of the device: TOTIM® Codes T3000

Destinazione d'uso / Intended Use: TOTIM® è un cuscino in schiuma di poliuretano destinato all'immobilizzazione o al posizionamento del paziente. Completamente sigillato, è rivestito esternamente in microfibra di PET. Immobilizzazione dei pazienti sottoposti a radioterapia o posizionamento del paziente durante l'intervento chirurgico.

TOTIM® is a polyurethane foam cushion for patient immobilization or positioning. Fully sealed, its outer material is PET microfiber. Immobilization of radiotherapy patients or positioning patient during surgery.

Basic UDI-DI: 80580452T3000BY Medical Device Class I Not Sterile

European Authorised Representative (EO ACTOR):

Alessandra Bolzon

Email: quality@totim.it

Classificazione / Classification: Dispositivo Medico di Classe I (Non Sterile), in accordo alla Regola 1 dell'Allegato VIII del Regolamento (UE) 2017/745.

Class I Medical Device (Non-Sterile), according to Rule 1 of Annex VIII of Regulation (EU) 2017/745.

Dichiarazione / Declaration: Si dichiara che il dispositivo medico sopra menzionato soddisfa i Requisiti Generali di Sicurezza e Prestazione previsti dall'Allegato I del Regolamento (UE) 2017/745 (MDR) relativo ai dispositivi medici.

It is hereby declared that the above-mentioned medical device meets the General Safety and Performance Requirements of Annex I of the Medical Device Regulation (EU) 2017/745 (MDR).

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer ESSEBI MEDICAL SRL dba of TOTIM® Patient Cushion immobilization or positioning system.

Applicable Directives: EU Regulation 2017/745 (MDR) of The European Parliament and of the Council of 5 April 2017 on a Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Reference Codes:

UDI-DI	Description	Type	Codes	Qty	PCS	Package
8058045288732	NECK MP PROTON	NECK MP PROTON	T3010MPPTN	10	PCS	Internal Box
8058045288725	SKULL/SPINAL AXIS P PROTON	SKULL/SPINAL AXIS P PROTON	T3007PPTN	1	PCS	Internal Box
8058045288718	NECK M PROTON	NECK M PROTON	T3010MPTN	10	PCS	Internal Box
8058045288701	CERVICAL M PROTON	CERVICAL M PROTON	T3005MPTN	2	PCS	Internal Box
8058045288695	JOLLY S PROTON	JOLLY S PROTON	T3020SPTN	2	PCS	Internal Box
8058045286899	SKULL/SPINAL AXIS S PROTON	SKULL/SPINAL AXIS S PROTON	T3008SPTN	1	PCS	Internal Box
8058045288688	SKULL/SPINAL AXIS PROTON	SKULL/SPINAL AXIS PROTON	T3008PTN	1	PCS	Internal Box
UDI-DI	Description	Type	Codes	Qty	PCS	Package
8058045288671	TOTAL BODY	TOTAL BODY	T3009	1	PCS	Internal Box
8058045283553	JOLLY	P	T3002P	2	PCS	Internal Box
8058045280323	NECK	M	T3010M	10	PCS	Internal Box
8058045280224	BODY	L	T3001L	1	PCS	Internal Box
8058045280248	JOLLY		T3002	1	PCS	Internal Box
8058045280866	T SHAPE	T	T3015T	1	PCS	Internal Box
8058045280231	BODY	XL	T3001XL	1	PCS	Internal Box
8058045280255	LEG		T3004	1	PCS	Internal Box
8058045280262	CERVICAL	S	T3005S	2	PCS	Internal Box
8058045280286	LIMB		T3006	2	PCS	Internal Box
8058045280279	CERVICAL	M	T3005M	2	PCS	Internal Box
8058045280309	ARM		T3003	1	PCS	Internal Box
8058045280293	NECK	XS	T3010XS	10	PCS	Internal Box
8058045280316	NECK	S	T3010S	10	PCS	Internal Box
8058045285540	LIMB	P	T3006P	2	PCS	Internal Box
8058045280569	CERVICAL	P	T3015P	2	PCS	Internal Box
8058045280576	NECK	XSP	T3010XSP	10	PCS	Internal Box
8058045280583	NECK	MP	T3010MP	10	PCS	Internal Box
8058045280590	SPINAL/SKULL AXIS	P	T3007P	1	PCS	Internal Box
8058045280606	SPINAL/SKULL AXIS	S	T3008S	1	PCS	Internal Box
8058045280613	NECK		T3012	10	PCS	Internal Box

8058045280347	SPINAL/SKULL AXIS		T3008	1	PCS	Internal Box
8058045280354	BODY	P	T3001P	1	PCS	Internal Box
UDI-DI	Description	Type	Codes	Qty	PCS	Package
8058045280620	BODY	L	T3001L	5	PCS	Pallet Box
8058045280637	BODY	XL	T3001XL	5	PCS	Pallet Box
8058045280644	JOLLY		T3002	5	PCS	Pallet Box
8058045280651	ARM		T3003	5	PCS	Pallet Box
8058045280675	CERVICAL	S	T3005S	10	PCS	Pallet Box
8058045280682	CERVICAL	M	T3005M	10	PCS	Pallet Box
8058045280699	LIMB		T3006	10	PCS	Pallet Box
8058045280705	NECK	XS	T3010XS	50	PCS	Pallet Box
8058045280712	NECK	S	T3010S	50	PCS	Pallet Box
8058045280729	NECK	M	T3010M	50	PCS	Pallet Box
8058045280750	SPINAL/SKULL AXIS		T3008	5	PCS	Pallet Box
8058045280767	SPINAL/SKULL AXIS	S	T3008S	5	PCS	Pallet Box
8058045280774	BODY	P	T3001P	5	PCS	Pallet Box
8058045280781	JOLLY	P	T3002P	10	PCS	Pallet Box
8058045280798	LIMB	P	T3006P	10	PCS	Pallet Box
8058045280804	CERVICAL	P	T3015P	10	PCS	Pallet Box
8058045288848	SKULL/SPINAL AXIS	P PROTON	T3007PPTN	5	PCS	Pallet Box
8058045280002	NECK	XS	T3010XS	50	PCS	Pallet Box
8058045289012	NECK	MP PROTON	T3010MPPTN	50	PCS	Pallet Box
8058045289005	NECK	M PROTON	T3010MPTN	50	PCS	Pallet Box
8058045288992	NECK	MP	T3010MP	50	PCS	Pallet Box
8058045288985	NECK	XSP	T3010XSP	50	PCS	Pallet Box
8058045288916	NECK	S	T3010S	20	PCS	Pallet Box
8058045288909	NECK	M	T3010M	20	PCS	Pallet Box
8058045288893	NECK	XSP	T3010XSP	20	PCS	Pallet Box
8058045288886	NECK	MP	T3010MP	20	PCS	Pallet Box
8058045288879	NECK	M PROTON	T3010MPTN	20	PCS	Pallet Box
8058045288862	NECK	MP PROTON	T3010MPPTN	20	PCS	Pallet Box
8058045288824	CERVICAL	M PROTON	T3005MPTN	10	PCS	Pallet Box
8058045288817	JOLLY	S PROTON	T3020SPTN	10	PCS	Pallet Box
8058045288800	SKULL/SPINAL AXIS S PROTON	S PROTON	T3008SPTN	5	PCS	Pallet Box
8058045288794	SKULL/SPINAL AXIS	PROTON	T3008PTN	5	PCS	Pallet Box
8058045288787	NECK	MP	T3010MP	50	PCS	Pallet Box
8058045288770	NECK	XSP	T3010XSP	50	PCS	Pallet Box

UDI-DI	Description	Type	Codes	Qty	PCS	Package
8058045288763	SKULL/SPINAL AXIS P	P	T3007P	5	PCS	Pallet Box
8058045288756	TOTAL BODY	TOTAL BODY	T3009	2	PCS	Pallet Box
8058045288749	T SHAPE	T	T3015T	5	PCS	Pallet Box
8058045281399	BODY	XXL	T3001	1	PCS	Internal Box
8058045281405	BODY	XXL	T3001	5	PCS	Pallet Box

Intended Purpose: Immobilization of radiotherapy patients or positioning patient during surgery

Date, September 10th 2026

Alessandra Bolzon



**European Authorised Representative
(EO ACTOR)**

Arch. Pietro Sordina

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