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
47896 Faetano, RSM
Phone: +379 0549 973858
Email: quality@totim.it
www.totim.it
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):
ID/SRN: IT-AR-000036939
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

ESSEBI MEDICAL Srl -TOTIM®
Strada Campo del Fiume 84 - 47896 Faetano Repubblica di San Marino - C.O.E. SM26889 Tel. +378 0549 963858
www.totim.it e-mail: info@totim.it PEC: totim@pec.totim.it – Registro impresa n. 7577

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

ESSEBI MEDICAL Srl -TOTIM®
Strada Campo del Fiume 84 - 47896 Faetano Repubblica di San Marino - C.O.E. SM26889 Tel. +378 0549 963858
www.totim.it e-mail: info@totim.it PEC: totim@pec.totim.it – Registro impresa n. 7577

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

ESSEBI MEDICAL Srl -TOTIM®
Strada Campo del Fiume 84 - 47896 Faetano Repubblica di San Marino - C.O.E. SM26889 Tel. +378 0549 963858
www.totim.it e-mail: info@totim.it PEC: totim@pec.totim.it – Registro impresa n. 7577

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

ESSEBI MEDICAL s.r.l.
Strada Campo del Fiume, 84
47896 Faetano - R.S.M.
C.O.E. SM 26889
Repubblica di San Marino

CEO
ESSEBI MEDICAL SRL dba TOTIM®

ESSEBI MEDICAL Srl -TOTIM®
Strada Campo del Fiume 84 - 47896 Faetano Repubblica di San Marino - C.O.E. SM26889 Tel. +378 0549 963858
www.totim.it e-mail: info@totim.it PEC: totim@pec.totim.it – Registro impresa n. 7577