

DECLARATION OF CONFORMITY

Date, May 16th 2022

Manufacturer: ESSEBI MEDICAL SRL dba TOTIM®

Medical Device: TOTIM® Patient Cushion Immobilization system

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European Authorised Representative (EO ACTOR):

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SRN:

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

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

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
8058045281214	JOLLY S	S	T3002 S	2	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
8058045280354	BODY	P	T3001P	1	PCS	InternalBox

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
8058045281221	JOLLY S	S	T3002 S	10	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
8058045280668	LEG		T3004	5	PCS	Pallet Box

Intended Purpose: Immobilization of radiotherapy patients

Risk Class: Class I Medical Device (Annex VIII, Rule 1, MDR 2017/745)

Under my sole responsibility, we state that the above mentioned products meet all the applicable general and security requirements of Annex I of the EU Medical Devices Regulation and all the applicable standards.

The Manufacturer undertakes to keep available for the Competent Authorities the Technical Documentation quoted in Annex II of (EU) Regulation 2017/745 for a period of at least 10 years after the last manufacture of the product.

Francesco Pontara



**European Authorised Representative
(EO ACTOR)**

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