

Declaration of Conformity



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

MANUFACTURER		
Name of Company	Address	SRN
TheraTogs, Inc.	305 Society Drive STE C-3 Telluride CO 81435-8902 USA PH: 01.970.239.0098 globalsales@theratogs.com	US-MF-000001407

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
MedEnvoy Global B.V.	Prinses Margrietplantsoen 33 STE 123 2595AM The Hague The Netherlands	NL-AR-000024028	PH: 31.70.326.2148 EU-AR@medenvoyglobal.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
TheraTogs ULTRA orthotic garment systems	See Exhibit A for model name(s) and/or catalog numbers
TherAlign Dragonfly TLSO Accessory Kits	See Exhibit B for model name(s) and/or catalog numbers
Intended Purpose	Basic UDI-DI
TheraTogs are orthotic undergarment and strapping systems intended to provide carryover of rehabilitation activities for neuromotor, sensory, and postural training. The Dragonfly TLSO Accessory Kit is intended to facilitate carryover of standard of care rehabilitation activities in the management of trunk alignment and postural deficits occurring under conditions such as osteoporosis, thoracic or spinal muscle strain or sprain, spinal stress or compression fractures, truncal hypotonia, and other postural issues.	See Exhibits A and B for UDI-DI(s)

RISK CLASS FOR DEVICES	
Device Classification	Common Specifications / Standards
Class: Class 1	21 CFR 820 • Food and Drug Administration Code of Federal Regulations - Quality System Regulation FDA-89-4203: (1989) – Labeling: Regulatory-Requirements-for-Medical-Devices
Rule: Rule 1	ISO 13485: 2016 • Medical devices – Quality Management Systems – Requirements for Regulatory Purposes ISO 20417:2021 – Medical devices – Information to be supplied by the Manufacturer

TheraTogs, Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Sylva Hamilton
TITLE: Director of Operations
PLACE: Montrose, Colorado USA
DATE: 06 September 2024

SIGNATURE:

Exhibit A: TheraTogs ULTRA Orthotic Garment Systems

Brand	Device Group	Item Number	Description	Basic UDI
TheraTogs	Clinical Starter Systems	GCS512	Clinical Starter System, Infant, Preschool	8100494GCS5XY
TheraTogs	Clinical Starter Systems	GCS523	Clinical Starter System, Pediatric	
TheraTogs	Clinical Starter Systems	GCS534	Clinical Starter System, Pediatric/Junior	
TheraTogs	Clinical Starter Systems	GCS546	Clinical Starter System, Adult	
TheraTogs	Clinical Starter Systems	GWZCSS-1	Wunzi Clinical Starter Sys. (0 to 12 month)	
TheraTogs	Clinical Starter Systems	GWZCSS-2	Wunzi Clinical Starter Sys. (3 to 18) month	
TheraTogs	Clinical Starter Systems	GWZCSS-3	Wunzi Clinical Starter Sys. (12 to 24)	
TheraTogs	Clinical Starter Systems	GWZCSS-4	Wunzi Sizing Kit, 12-24 mos	8100494CTFBL
TheraTogs	CTF Training Systems	CTF-1 400	Training/Demo System – Small	
TheraTogs	CTF Training Systems	CTF-1 600	Training/Demo System – Med/Large	
TheraTogs	CTF Training Systems	CTF-1 620	Training/Demo System – X Large	
TheraTogs	CTF Training Systems	CTF-2 400	Training/Demo System – Small	
TheraTogs	CTF Training Systems	CTF-2 600	Training/Demo System – Med/Large	
TheraTogs	CTF Training Systems	CTF-2 620	Training/Demo System – X Large	8100494DFAA5
TheraTogs	Dorsiflexion Assist DFA Systems	DFA204C	Infant 3-6, Toddler 6.5-8.5 & DFA204C Pre-Walking 3-6	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA304C	Girls & Boys 9-13 1/2 & 1-2 & DFA 304C Girls & Boys 9-13.5 & 1-2	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA314C	Girls & Boys 3-6 & DFA 314C Girls & Boys 3-6	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA404C	Girls/Women 5-8.5, Boys/Men 7-9.5 & DFA 404C Women 5-6, Men 6-7	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA504C	Women & Men 9-10 & DFA 504C Women 7-8, Men 8-9	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA604C	Women & Men 11-12 & DFA 604C Women 9-11, Men 10-11	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA204G	Infant 3-6, Toddler 6.5-8.5	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA304G	Girls & Boys 9-13 1/2 & 1-2	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA314G	Girls & Boys 3-6	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA404G	Girls/Women 5-8.5, Boys/Men 7-9.5	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA504G	Women & Men 9-10	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA604G	Women & Men 11-12	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA104S	Infant 2 – Toddler 6	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA204S	Pre-Walking 3-6	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA304S	Girls & Boys 9-13.5 & 1-2	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA314S	Girls & Boys 3-6	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA404S	Women 5-6, Men 6-7	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA504S	Women 7-8, Men 8-9	
TheraTogs	Dorsiflexion Assist DFA Systems	DFA604S	Women 9-11, Men 10-11	
TheraTogs	Full Body Systems	GFB100	TheraTogs ULTRA Full Body Sys: Infant	8100494GFBAN
TheraTogs	Full Body Systems	GFB200	TheraTogs ULTRA Full Body Sys: Pre-School	
TheraTogs	Full Body Systems	GFB300	TheraTogs ULTRA Full Body Sys: Pediatric	
TheraTogs	Full Body Systems	GFB400	TheraTogs ULTRA Full Body Sys: Petite Adult	
TheraTogs	Full Body Systems	GFB600	TheraTogs ULTRA Full Body Sys: Adult Fem Small	
TheraTogs	Full Body Systems	GFB620	TheraTogs ULTRA Full Body Sys: Adult Fem Large	
TheraTogs	Full Body Systems	GFB700	TheraTogs ULTRA Full Body Sys: Adult Male Small	
TheraTogs	Full Body Systems	GFB720	TheraTogs ULTRA Full Body Sys: Adult Male Large	
TheraTogs	Full Body Systems	GFB730	TheraTogs ULTRA Full Body Sys: Adult Male X-Large	8100494GLEBE
TheraTogs	Lower Extremity Systems	GLE101	TheraTogs ULTRA Lower Extremity Sys: Infant	
TheraTogs	Lower Extremity Systems	GLE201	TheraTogs ULTRA Lower Extremity Sys: Pre-School	
TheraTogs	Lower Extremity Systems	GLE301	TheraTogs ULTRA Lower Extremity Sys: Pediatric	
TheraTogs	Lower Extremity Systems	GLE401	TheraTogs ULTRA Lower Extremity Sys: Junior	
TheraTogs	Lower Extremity Systems	GLE601	TheraTogs ULTRA Lower Extremity Sys: Adult Fem Small	
TheraTogs	Lower Extremity Systems	GLE621	TheraTogs ULTRA Lower Extremity Sys: Adult Fem Large	
TheraTogs	Lower Extremity Systems	GLE701	TheraTogs ULTRA Lower Extremity Sys: Adult Male Small	
TheraTogs	Lower Extremity Systems	GLE721	TheraTogs ULTRA Lower Extremity Sys: Adult Male Large	8100494GWTD
TheraTogs	Lower Extremity Systems	GLE731	TheraTogs ULTRA Lower Extremity Sys: Adult Male X-Large	
TheraTogs	Pediatric Wrist & Thumb Positioning Systems	GWT307R	TheraTogs ULTRA Wrist & Thumb Positioning Sys: Small Pediatric, Right Hand	
TheraTogs	Pediatric Wrist & Thumb Positioning Systems	GWT307L	TheraTogs ULTRA Wrist & Thumb Positioning Sys: Small Pediatric, Left Hand	
TheraTogs	Pediatric Wrist & Thumb Positioning Systems	GWT317R	TheraTogs ULTRA Wrist & Thumb Positioning Sys: Med/Large Pediatric, Right Hand	8100494GPTAYY
TheraTogs	Pediatric Wrist & Thumb Positioning Systems	GWT317L	TheraTogs ULTRA Wrist & Thumb Positioning Sys: Med/Large Pediatric, Left Hand	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA110	TheraTogs ULTRA Posture & Trunk Alignment (PTA) Sys: Infant	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA210	TheraTogs ULTRA Posture & Trunk Alignment (PTA) Sys: Pre-School	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA310	TheraTogs ULTRA Posture & Trunk Alignment (PTA) Sys: Pediatric	8100494GPTAYY
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA410	TheraTogs ULTRA Posture & Trunk Alignment (PTA) Sys: Junior	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA610	TheraTogs ULTRA Posture & Torso Alignment (PTA) Sys: Female Sm/Medium Adult	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA620	TheraTogs ULTRA Posture & Torso Alignment (PTA) Sys: Female Large Adult	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA710	TheraTogs ULTRA Posture & Torso Alignment (PTA) Sys: Male Sm/Medium Adult	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA720	TheraTogs ULTRA Posture & Torso Alignment (PTA) Sys: Male Large Adult	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA730	TheraTogs ULTRA Posture & Torso Alignment (PTA) Sys: Male X-Large Adult	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2110	TheraTogs Dual ULTRA Posture & Trunk Alignment (PTA) Sys: Infant	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2210	TheraTogs Dual ULTRA Posture & Trunk Alignment (PTA) Sys: Pre-School	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2310	TheraTogs Dual ULTRA Posture & Trunk Alignment (PTA) Sys: Pediatric	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2410	TheraTogs Dual ULTRA Posture & Trunk Alignment (PTA) Sys: Junior	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2610	TheraTogs DUAL Medium Adult Female Posture Torso Alignment System	

Brand	Device Group	Item Number	Description	Basic UDI
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2620	TheraTogs DUAL Large Adult Female Posture Torso Alignment System	8100494GPTAYY
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2710	TheraTogs DUAL Medium Adult Male Posture Torso Alignment System	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA2720	TheraTogs Dual Large Adult Male Posture Torso Alignment System	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA110TTG	Togs2Grow Infant + Preschool Posture Torso Alignment System	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA210TTG	Togs2Grow Preschool + Pediatric Posture Torso Alignment System	
TheraTogs	Posture & Torso Alignment (PTA) Systems	GPTA310TTG	Togs2Grow Pediatric + Junior Posture Torso Alignment System	8100494SUSH
TheraTogs	Sit-Up (SU) Systems	SU100	Sit-Up System Extra Small	
TheraTogs	Sit-Up (SU) Systems	SU200	Sit-Up System Small	
TheraTogs	Sit-Up (SU) Systems	SU300	Sit-Up System Medium	
TheraTogs	Sit-Up (SU) Systems	SU400	Sit-Up System Large	8100494PATRZN
TheraTogs	TogRite Strapping Assembly	PATR110	TogRite Strapping – 1.5” Wide x 10 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR125	TogRite Strapping – 1.5” Wide x 25 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR201	TogRite Strapping - 2” Wide x 1 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR202	TogRite Strapping - 2” Wide x 2 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR203	TogRite Strapping - 2” Wide x 3 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR210	TogRite Strapping – 2” Wide x 10 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR225	TogRite Strapping – 2” Wide x 25 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR301	TogRite Strapping - 3” Wide x 1 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR302	TogRite Strapping - 3” Wide x 2 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR303	TogRite Strapping – 3” Wide x 3 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR310	TogRite Strapping – 3” Wide x 10 Yard Roll	
TheraTogs	TogRite Strapping Assembly	PATR325	TogRite Strapping – 3” Wide x 25 Yard Roll	8100494GWZDR
TheraTogs	Wunzi Infant Systems	GWZ25	TheraTogs Ultra Wunzi Infant Sys: XX Small	
TheraTogs	Wunzi Infant Systems	GWZ50	TheraTogs Ultra Wunzi Infant Sys: X Small	
TheraTogs	Wunzi Infant Systems	GWZ75	TheraTogs Ultra Wunzi Infant Sys: Small	
TheraTogs	Wunzi Infant Systems	GWZ100	TheraTogs Ultra Wunzi Infant Sys: Medium	
TheraTogs	Wunzi Infant Systems	GWZ125	TheraTogs Ultra Wunzi Infant Sys: Large	
TheraTogs	Wunzi Infant Systems	GWZLKS	TheraTogs Ultra Wunzi Limb Kit: Small	
TheraTogs	Wunzi Infant Systems	GWZLKL	TheraTogs Ultra Wunzi Limb Kit: Large	
TheraTogs	Wunzi Infant Systems	GWZ25KT	XXSmall Wunzi Infant System w/ Small Limb Kit	
TheraTogs	Wunzi Infant Systems	GWZ50KT	XSmall Wunzi Infant System w/ Small Limb Kit	
TheraTogs	Wunzi Infant Systems	GWZ75KT	Small Wunzi Infant System w/ Large Limb Kit	
TheraTogs	Wunzi Infant Systems	GWZ100KT	Medium Wunzi Infant System w/ Large Limb Kit	
TheraTogs	Wunzi Infant Systems	GWZ125KT	Large Wunzi Infant System w/ Large Limb Kit	
TheraTogs	Wunzi Infant Systems	GWZ25TTG	TheraTogs Ultra Wunzi Sys: XX Small + X Small	
TheraTogs	Wunzi Infant Systems	GWZ50TTG	TheraTogs Ultra Wunzi Sys: X Small + Small	
TheraTogs	Wunzi Infant Systems	GWZ75TTG	TheraTogs Ultra Wunzi Sys: Small + Medium	
TheraTogs	Wunzi Infant Systems	GWZ100TTG	TheraTogs Ultra Wunzi Sys: Medium + Large	

Exhibit B: TherAlign TLSO Systems

TherAlign	DragonFly TLSO Systems	DFLY30A	DFLY30A Dragonfly TLSO D30 Accessory Kit	8100494DFLYXH
TherAlign	DragonFly TLSO Systems	DFLY33A	DFLY33A Dragonfly TLSO D33 Accessory Kit	
TherAlign	DragonFly TLSO Systems	DFLY40A	DFLY40A Dragonfly TLSO D40 Accessory Kit	
TherAlign	DragonFly TLSO Systems	DFLY48A	DFLY48A Dragonfly TLSO D48 Accessory Kit	
TherAlign	DragonFly TLSO Systems	DFLY53A	DFLY53A Dragonfly TLSO D53 Accessory Kit	