



EC DECLARATION OF CONFORMITY CERTIFICATE

We, the company Thorwear Inc. (dba Elevate Movement), 5674 El Camino Real, Ste N, Carlsbad CA 92008, United States, hereby declare on our own responsibility that the following Class I product ranges meet all applicable Essential requirements of the MDR Art. 52 & Annex II, III.

Class I products follow the procedure set out in MDR 2017/745 ANNEX VIII. Thorwear Inc. runs a quality system according to ISO 13485:2012

Should you require more detailed information regarding this EC declaration of conformity, please contact Thorwear Inc.'s Head Office or our European Authorized Representative veomedical GmbH.

This declaration is valid and updated from April 24th, 2025.

Single registration Number (SRN): **US-MF-000038778**

Intended use: The dynamic foot lift orthosis AFO1 Glide, AFO1 FreeFlow, AFO1 Swift System, AFO1 HelixBand, and the Sstep are medical devices to support the dorsi- and plantar- flexor muscle weakness. The devices are intended to lift the foot during swing phase to reduce drop-foot and the risk of catching the toe in mid-swing. The use of carbon fibre in the Glide, FreeFlow, and Swift ankle orthoses provides energy return throughout the phases of gait improving the individual's overall functionality. They are also used to correct foot position during stance in up to 3 planes.

Product Classification	Joint	Product Name	Specification	Classification	GMDN Code	Basic UDI-DI	UDI-DI	Valid from date (yyyy/mm/dd)	Discontinued
Orthotics	Ankle External Brace	AFO1 FreeFlow	Right	Class I	36206	08600028390FFLOWLJ	00860002839028	2024/01/01	
Orthotics	Ankle External Brace	AFO1 FreeFlow	Left	Class I	36206	08600028390FFLOWLJ	00860002839035	2024/01/01	
Orthotics	Ankle External Brace	AFO1 Glide	Right	Class I	36206	08600028390GLIDEKK	00860002839042	2024/01/01	
Orthotics	Ankle External Brace	AFO1 Glide	Left	Class I	36206	08600028390GLIDEKK	00860002839059	2024/01/01	
Orthotics	Ankle External Brace	AFO1 HelixBand FreeFlow	n/a	Class I	36206	08600028390FFLOWLJ	00860002839066	2024/01/01	
Orthotics	Ankle External Brace	AFO1 HelixBand Glide	n/a	Class I	36206	08600028390GLIDEKK	00860002839073	2024/01/01	
Orthotics	Ankle External Brace	AFO1 Swift System Posterior	Right	Class I	36206	0850033914SWIFTZ7	00850033914030	2024/01/01	
Orthotics	Ankle External Brace	AFO1 Swift System Posterior	Left	Class I	36206	0850033914SWIFTZ7	00850033914047	2024/01/01	
Orthotics	Ankle External Brace	AFO1 Swift System Anterior	Right	Class I	36206	0850033914SWIFTZ7	00850033914054	2024/01/01	
Orthotics	Ankle External Brace	AFO1 Swift System Anterior	Left	Class I	36206	0850033914SWIFTZ7	00850033914061	2024/01/01	
Orthotics	Ankle External Brace	Sstep	Small Athletic	Class I	36206	0850033914SSTEPZP	00850033914177	2025/01/01	
Orthotics	Ankle External Brace	Sstep	Small	Class I	36206	0850033914SSTEPZP	00850033914139	2025/01/01	
Orthotics	Ankle External Brace	Sstep	Medium Athletic	Class I	36206	0850033914SSTEPZP	00850033914184	2025/01/01	
Orthotics	Ankle External Brace	Sstep	Medium	Class I	36206	0850033914SSTEPZP	00850033914146	2025/01/01	
Orthotics	Ankle External Brace	Sstep	Large Athletic	Class I	36206	0850033914SSTEPZP	00850033914191	2025/01/01	
Orthotics	Ankle External Brace	Sstep	Large	Class I	36206	0850033914SSTEPZP	00850033914153	2025/01/01	
Orthotics	Ankle External Brace	Sstep	XLarge	Class I	36206	0850033914SSTEPZP	00850033914160	2025/01/01	

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