



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 Medical Device Directive 93/42 EEC in Annex I.

Class I products follow the procedure set out in Annex VII. 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 January 19th, 2024.

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

Intended use: The dynamic foot lift orthoses Glide, FreeFlow, Swift System and HelixBand are ankle orthosis to support 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 fiber 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	Classification	GMDN Code	Valid from date (yyyy/mm/dd)	Discontinued
Orthotics	Ankle External Brace	AFO1 FreeFlow	Class I	36206	2024/01/19	
Orthotics	Ankle External Brace	AFO1 Glide	Class I	36206	2024/01/19	
Orthotics	Ankle External Brace	AFO1 HelixBand	Class I	36206	2024/01/19	
Orthotics	Ankle External Brace	AFO1 Swift System	Class I	36206	2024/01/19	

LOCAL ACTOR ID/SRN DE-AR-000038460

veomedical GmbH
Enzianweg 8
50259 Pulheim
Germany
hallo@veomedical.de

Matthew Hollister
Chief Operating Officer Thorwear Inc. /PPRC

Matt Hollister