SPANLINK INTERNATIONAL

EU Declaration of Conformity

The following description for the medical device,

Device information	***Description***
Common device name	*Ankle/Foot Orthosis*
Registered trade name or trade mark	*b:joynz*
EU Single Registration Number (SRN)	*US-MF-000012261*
Authorized representative	*CMC Medical devices & Drugs S.L.* *C/ Horacio Lengo n18, C.P 29006 Málaga-Spain*
Product series	*b:joynz air walker soft tall*
Basic UDI-DI	*0810084338001004WE*
Risk class of the device	*Class I*
Common Specification (CS) references	*Extra-Small, Small, Medium, Large, Extra-Large*
Intended purpose	*The b:joynz air walker soft is a medical device. It is an orthosis for the lower leg and foot to provide immobilization in a specified position.* *Indications: Conservative/post-operative care for the foot & ankle; Immobilization of the lower leg/foot region; Ankle sprains (severe); Stable fractures; Soft tissue injuries*

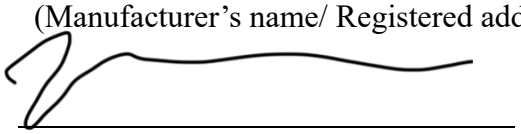
That is covered by the present declaration is in conformity with the **Medical Device Regulation (EU) 2017/745**, and comply with the General Safety and Performance Requirements according to Annex I of the Medical Device Regulation (EU) 2017/745.
The products have been classified according to Annex VIII, Chapter III, MDR 2017/745 in risk class I. They correspond to the give provisions of the Regulation (EU) 2017/745 for Medical Devices.

The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a general rule, under the sole responsibility of the manufacturer. The class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 “EC declaration of conformity” after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

Issued date: October 21, 2025
Version: V12.0

The following person is exclusively responsible for the compliance of declaration:

Span Link International LLC
28 W Jefryn Blvd, Deer Park, NY 11729, USA
(Manufacturer's name/ Registered address)



Vincent A. Benenati / CEO

October 21, 2025