EU Declaration of Conformity

Span Link International LLC
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11729 Deer Park, NY, USA
Single Registration Number (SRN): US-MF-000012261

Hereby declares under own responsibility, that the following products comply with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product name	DONJOY® Nextep Xcel Tall DONJOY® Nextep Xcel Ankle DONJOY® Nextep Xcel Air Tall DONJOY® Nextep Xcel Air Ankle DONJOY® Nextep Xcel Lite Tall
Basic UDI-DI	*08100843382112EG*
EMDN	*Y061206 - Orthosis, ankle-foot*
Intended purpose	Intended Use/ Indications (Nextep Xcel Tall, Nextep Xcel Air Tall, and Nextep Xcel Lite Tall): designed to provide post-operative or post-traumatic support and immobilization to the ankle or foot. It may be suitable for severe ankle sprains, stable fractures of the lower leg and ankle, stable fractures of the foot and Achilles tendon repairs. Intended Use/ Indications (Nextep Xcel Tall, Nextep Xcel Air Tall, and Nextep Xcel Lite Tall): designed to provide support and immobilization to the foot and ankle. It may be suitable for the treatment of severe ankle sprains, soft tissue injuries of the foot and ankle, stress fractures of the foot, stable fractures of the foot, and ligamentous injuries such as Plantar Fasciitis.
Medical Device Classification	*Class I Device* according to Rule 1 in the Annex VIII, Chapter III, MDR 2017/745/EU as amended by 2020/561/EU
Conformity assessment procedure	*Annexes II and III of MDR* (Technical Documentation and PMS documentation).

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485 and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

Issued date: September 11, 2025

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European authorized representative	*CMC Medical Devices & Drugs SL with SRN ES-AR-000000293 and located in C/ Horacio Lengo no 18, CP 29006, Málaga, Spain.*

Date of issue: September 11, 2025



(Compiled and released)

Vincent A Benenati, CEO, Span Link International LLC

Product description	**Part number**
NEXTEP XCEL, ANKLE, S	82-112-S
NEXTEP XCEL, ANKLE, M	82-112-M
NEXTEP XCEL, ANKLE, L	82-112-L
NEXTEP XCEL, TALL, S	82-114-S
NEXTEP XCEL, TALL, M	82-114-M
NEXTEP XCEL, TALL, L	82-114-L
NEXTEP XCEL LITE, TALL, S	82-115-S
NEXTEP XCEL LITE, TALL, M	82-115-M
NEXTEP XCEL LITE, TALL, L	82-115-L
NEXTEP XCEL AIR, ANKLE, S	82-116-S
NEXTEP XCEL AIR, ANKLE, M	82-116-M
NEXTEP XCEL AIR, ANKLE, L	82-116-L
NEXTEP XCEL AIR, TALL, S	82-118-S
NEXTEP XCEL AIR, TALL, M	82-118-M
NEXTEP XCEL AIR, TALL, L	82-118-L