EC Declaration of Conformity

Night Splint Wedge

Manufacturers Name:	DARCO International, Inc.
Manufacturer's Address:	810 Memorial Boulevard Huntington WV 25701 United States of America
SRN	US-MF-000016195
Authorized Representative Name:	DARCO (Europe) GmbH
Authorized Representative Address:	Gewerbegebiet 18 Raisting D-82399 Germany
SRN	DE-AR-000010120

Name of Device US	Product Code US	Name of Device EU	Product Code EU	UDI-DI
Night Splint Wedge S	NW1B	NightSplint S	NS1B	00609271809659
Night Splint Wedge M	NW2B	NightSplint M	NS2B	00609271809758
Night Splint Wedge L	NW3B	NightSplint L	NS3B	00609271809857
Night Splint Wedge XL	NW4B	NightSplint XL	NS4B	00609271809956

Basic-UDI	0609271NWRF
GMDN:	36206
EMDN:	Y06120601
UMDNS:	17-873

Intended Purpose: The Body Armor Night Splint Wedge is indicated for the treatment of Plantar Fasciitis, Achilles Tendonitis, shortening of the plantar fascia and postoperative immobilization. The Night Splint Wedge achieves its intended purpose by immobilization of the lower leg and ankle while applying an increasing stretch of the plantar surface and Achilles tendon via placement of wedges under the metatarsal surface. The Body Armor Night Splint is available in 4 sizes.

Classification:	Class 1
Notified Body Name:	Not Applicable
Notified Body Address:	Not Applicable
Notified Body Identification Number:	Not Applicable
Standards Applied:	ISO 14971:2019 ISO 15223-1:2016 ISO 20416:2020 ISO 1041:2013 MEDDEV 2.7/1 MDR 2017/745
Conformity Assessment Route:	DARCO International, Inc. uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745: Class 1: EC conformity declaration according to Annex VIII, Chapter 3, 4.1, Rule 1

We declare under our sole responsibility that the above listed medical devices according to Annex IV of Regulation (EU) 2017/745 (MDR) meet all applicable basic safety and performance requirements.

This declaration is supported by the manufacturers quality management system compliant with (EU) MDR 2017/745 Chapter 2, Article 10, section 9 (a) – (m) and also US FDA CFR21 § 820.

This declaration is valid until a change in one of the products specified in this document or not later than 5 years from the date of signing.

Signed for the Manufacturer by Mark S. Cooper as its Director of Regulatory Affairs on the 19th day of January, 2022.

Signature: Mark S. Cooper