EC Declaration of Conformity

Body Armor Night Splint

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	ProductCode US	Product Code EU	UDI-DI
Body Armor Night Splint Small		BADS-S	00609271899162
Body Armor Night Splint Standard	BADS	BADS	00609271899964

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

Intended Purpose: The Body Armor Night Splint is indicated for the treatment of Plantar Fasciitis, Heel Spurs, Achilles Tendonitis, Achilles Tendinosis, Metatarsalgia and ankle contracture. The Body Armor Night Splint achieves its intended use by engaging the windlass mechanism of the foot resulting in a

specific and sustained stretch to the plantar fascia and a sustained low load stretch to the flexor tendon, Achilles tendon and calf muscles. The Body Armor Night Splint is available in 2 sizes in Europe and 1 size in the United States.

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 this 19th day day of January 2022.

Signature: Mark S. Cooper