EC Declaration of Conformity

Body Armor Cast Shoe

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	**Product Code US**	**Product Code EU**	**UDI-DI**
Body Armor Cast Shoe XS	BACS0	CB0	00609271889057
Body Armor Cast Shoe S	BACS1	CB1	00609271889156
Body Armor Cast Shoe M	BACS2	CB2	00609271889255
Body Armor Cast Shoe L	BACS3	CB3	00609271889354
Body Armor Cast Shoe XL	BACS4	CB4	00609271889453
Body Armor Cast Shoe XXL	BACS5	CB5	00609271889552

Basic-UDI	0609271BACSUA
GMDN:	10667
EMDN:	Y063303
UMDNS:	10-667

Intended Purpose: The DARCO Body Armor Cast Shoe is specifically engineered to shield the cast from moisture, shock and everyday wear. The shoe can be used with fiberglass casts and bulky bandages.

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 26th day of January, 2022.

Signature: Mark S. Cooper