EC Declaration of Conformity

CBO Cast Boot Open Toe

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	Name of Device OBL1	Product Code US	Product Code EU	Product Code OBL1	UDI-DI
CBO XXS	CBO CS CAST SHOE 6,5 BLUE 1 TODDLER	CBOP	CBOP	71427-00023-00	00609271069718
CBO XS	CBO CS CAST SHOE XS BLUE 1	CBO0	CBO0	71427-00024-00	00609271069015
CBO S	CBO CS CAST SHOE S BLUE 1	CBO1	CBO1	71427-00025-00	00609271069114
CBO M	CBO CS CAST SHOE M BLUE 1	CBO2	CBO2	71427-00026-00	00609271069213
CBO L	CBO CS CAST SHOE L BLUE 1	CBO3	CBO3	71427-00027-00	00609271069312
CBO XL	CBO CS CAST SHOE XL BLUE 1	CBO4	CBO4	71427-00028-00	00609271069411
Cast Boot Pediatric XS	N/A	N/A	CB-PED1	N/A	00609271416093
Cast Boot Pediatric S	N/A	N/A	CB-PED2	N/A	00609271416192

Basic-UDI	0609271CBO9F
GMDN:	10667
EMDN:	Y063303
UMDNS:	10-667

Intended Purpose: The DARCO CBO Cast Boot is a low profile multi use cast boot intended to protect casts of all types and heavy compression 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 25th day of January, 2022.

Signature: Mark S. Cooper