EC Declaration of Conformity

Slimline Cast Boot

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
SlimLine XS	SLQ0B	SLO0B-ST	00609271849051
SlimLine S	SLQ1B	SLO1B-ST	00609271849150
SlimLine M	SLQ2B	SLO2B-ST	00609271849259
SlimLine L	SLQ3B	SLO3B-ST	00609271849358
SlimLine XL	SLQ4B	SLO4B-ST	00609271849457
SlimLine Pediatric S Round Toe Blue	SLO1NP		00609271056114
Slimline Pediatric M Round Toe Blue	SLO2NP		00609271056213
Slimline Pediatric L Round Toe Blue	SLO3NP		00609271056312
Slimline Pediatric S Square Toe Blue		SLP-1N	0609271846111
SlimLine Pediatric M Square Toe Blue		SLP-2N	00609271846210
SlimLine Pediatric L Square Toe Blue		SLP-3N	00609271846319
SlimLine Pediatric S Square Toe Pink		SLP-1P	00609271846135
SlimLine Pediatric M Square Toe Pink		SLP-2P	00609271846234
SlimLine Pediatric L Square Toe Pink		SLP-3P	00609271846333

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

Intended Purpose: The DARCO Slimline 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 16^{h} day of December, 2021

Signature: Mark S. Cooper