UKCA Declaration of Conformity

Slimline Cast Boot

Manufacturers Name: DARCO International, Inc.

Manufacturer's Address: 810 Memorial Boulevard
Huntington WV 25701
United States of America

UK Responsible Person Name: V-M Orthotics LTD

UK Responsible Person Address: Unit 25, Halesworth Business Centre
Norwich Road
Halesworth IP19 8QJ
United Kingdom

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 UKCA labelling of its products according to UK MDR 2002 as modified: Class 1: UKCA conformity declaration according to UK MDR 2002, Annex IX (as modified by Schedule 2A to the UK MDR 2002), Section III, Rule 1.

We declare under our sole responsibility that the above listed medical devices according to UK MDR Annex VII (as modified by Schedule 2A to the UK MDR 2002) meet all applicable basic safety and performance requirements.

This declaration is supported by the manufacturers quality management system compliant with ISO 13485:2016 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 Cooper as its Director of Regulatory Affairs on 9h day of December, 2022.

Signature: Mark Cooper