EC Declaration of Conformity

MedSurg Shoe

Manufacturers Name:	DARCO International, Inc.
Manufacturer's Address:	810 Memorial Boulevard Huntington WV 25701
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**
MedSurg Shoe MS	MQM1B	MSM1B-ST	00609271790117
MedSurg Shoe MM	MQM2B	MSM2B-ST	00609271790216
MedSurg Shoe ML	MQM3B	MSM3B-ST	00609271790315
MedSurg Shoe MXL	MQM4B	MSM4B-ST	00609271790414
MedSurg Shoe Pediatric	MQPB	MSPED-ST	00609271796515
MedSurg Shoe WS	MQW1B	MSW1B-ST	00609271793118
MedSurg Shoe WM	MQW2B	MSW2B-ST	00609271793217
MedSurg Shoe WL	MQW3B	MSW3B-ST	00609271793316

Basic-UDI	0609271HDPOCLP2
GMDN:	31041
EMDN:	Y063303
UMDNS:	13-576
Intended Purpose:	The DARCO MedSurg Shoe is intended to be worn to alleviate pain and pressure and to provide protection during the healing process for the foot post-surgery and post trauma.
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 17th December, 2021.

Signature: Mark S. Cooper