UK Declaration of Conformity

Classic Post Op Shoe

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	Name of Device OBL1	Product Code US	Product Code OBL1	UDI-DI
Classic Post Op Pediatric		HD-PO-CL1		00609271000902
Classic Post Op WS	Classic Post Op WS	HD-PO-CL2	72298-00050-00	00609271000919
Classic Post Op WM	Classic Post Op WM	HD-PO-CL3	72298-00051-00	00609271000926
Classic Post Op WL	Classic Post Op WL	HD-PO-CL4	72298-00052-00	00609271000933
Classic Post Op MS	Classic Post Op MS	HD-PO-CL5	72298-00053-00	00609271000940
Classic Post Op MM	Classic Post Op MM	HD-PO-CL6	72298-00054-00	00609271000957
Classic Post Op ML	Classic Post Op ML	HD-PO-CL7	72298-00055-00	00609271000964
Classic Post Op MXL	Classic Post Op MXL	HD-PO-CL8	72298-00056-00	00609271000971
Classic Post Op MXXL		HD-PO-CL9		0060927000988

Basic-UDI	0609271HDPOCLP2
GMDN:	31041
EMDN:	Y063303
UMDNS:	13-576

Intended Purpose:

The Classic Post Op 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 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 the 8th day of December, 2022.

Signature: *Mark Cooper*