EC Declaration of Conformity

Heelwedge Healing Shoe

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	ProductCode US	Product Code EU	UDI-DI
HeelWedge XS	HQ0B	HW0B-ST	00609271829053
HeelWedge S	HQ1B	HW1B-ST	00609271829152
HeelWedge M	HQ2B	HW2B-ST	00609271829251
HeelWedge L	HQ3B	HW3B-ST	00609271829350
HeelWedge XL	HQ4B	HW4B-ST	00609271829459

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

Intended Purpose: The DARCO HeelWedge is clinically proven to off-load pressure from the heel by shifting weight to the mid and forefoot to promote faster healing after surgery, trauma or when wounds or ulcerations are present on the heel.

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