EC Declaration of Conformity

Orthowedge 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
Orthowedge Pediatric		OW-PED	00609271819757
Orthowedge XS	OQ0B	OW0B-ST	00609271819054
Orthowedge S	OQ1B	OW1B-ST	00609271819153
Orthowedge M	OQ2B	OW2B-ST	00609271819252
Orthowedge L	OQ3B	OW3B-ST	00609271819351
Orthowedge XL	OQ4B	OW4B-ST	00609271819450

Basic-UDI	0609271OQR6
GMDN:	31041
EMDN:	Y063303
UMDNS:	13-576

Intended Purpose: The DARCO Orthowedge™ Healing Shoe promotes healing by reducing weight from the forefoot and may be used for any condition from the metatarsal heads distally in which it is desirable to reduce body with such as ulcers, infections, trauma and surgery.

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 25th day of January, 2022.

Signature: Mark S. Cooper