



EC Declaration of Conformity

WCS Wound Care System

Manufacturers Name: DARCO International, Inc.

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

SRN US-MF-000016195
(Single Registration Number)

Authorized Representative Name: DARCO (Europe) GmbH

Authorized Representative Address: Gewerbegebiet 18
Raisting D-82399
Germany

SRN DE-AR-000010120

Name of Device	Product Code US	Product Code EU	UDI-DI
WCS XS right		WCS0B/R	00609271258051
WCS XS left		WCS0B/L	00609271258068
WCSXS pair	WCS0B		00609271259058
WCS S right		WCS1B/R	00609271258150
WCS S left		WCS1B/L	00609271258167
WCS S pair	WCS1B		00609271259157
WCS S/M right		WCS7B/R	00609271258754
WCS S/M left		WCS7B/L	00609271258761
WCS S/M pair	WCS7B		00609271259751
WCS M right		WCS2B/R	00609271258259
WCS M left		WCS2B/L	00609271258266
WCS M pair	WCS2B		00609271259256
WCS L right		WCS3B/R	00609271258358
WCS L left		WCS3B/L	00609271258365
WCS L pair	WCS3B		00609271259355
WCS XL right		WCS4B/R	00609271258457
WCS XL left		WCS4B/L	00609271258464
WCS XL pair	WCS4B		00609271259454
WCS XXL right		WCS5B/R	00609271258556
WCS XXL left		WCS5B/L	00609271258563
WCS XXL pair	WCS5B		00609271259553
WCS /-Light Insoles XS left		WCI0/L	00609271279599
WCS /-Light Insoles XS right		WCI0/R	00609271279605
WCS /-Light Insoles	WCI0		00609271279179



XS pair			
WCS /-Light Insoles S left		WCI1/L	00609271279612
WCS /-Light Insoles S right		WCI1/R	00609271279629
WCS /-Light Insoles S pair	WCI1		00609271279186
WCS /-Light Insoles M left		WCI2/L	00609271279636
WCS /-Light Insoles M right		WCI2/R	00609271279643
WCS /-Light Insoles M pair	WCI2		00609271279193
WCS /-Light Insoles L left		WCI3/L	00609271279650
WCS /-Light Insoles L right		WCI3/R	00609271279667
WCS /-Light Insoles L pair	WCI3		00609271279292
WCS /-Light Insoles XL left		WCI4/L	00609271279674
WCS /-Light Insoles XL right		WCI4/R	00609271279681
WCS /-Light Insoles XL pair	WCI4		00609271279391
WCS /-Light Insoles XXL left		WCI5/L	00609271279698
WCS /-Light Insoles XXL right		WCI5/R	00609271279704
WCS /- Light Insoles XXL pair	WCI5		00609271279490
WCS /-Light Insoles S/M left		WCI7/L	00609271279711
WCS /-Light Insoles S/M right		WCI7/R	00609271279728
WCS /-Light Insoles S/M pair	WCI7		00609271279995

Basic UDI: 0609271WCSCW
 GMDN: 41575
 EMDN: Y061203
 UMDNS: 17-873

* Note that the WCS Wound Care System is offered in the United States in pairs and in Europe as each left or right.

Intended Purpose: The DARCO WCS Wound Care Shoe System is intended for the treatment of lesions through Wagner grade 3 ulcerations. The WCS achieves its intended use by means of a 4-layer multi density insole which may be modified thus effectively decreasing pressure from the plantar aspect of the foot. The WCS open toe version incorporates a leather upper which may also be modified or cut away to provide greater levels of pressure relief. Replacement insoles are available as an accessory for the DARCO WCS Wound Care System.



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 20th day of January, 2022.

Signature: *Mark S. Cooper*