EC Declaration of Conformity

Peg Assist Off-loading Devices

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	Product Code US	Product Code EU	UDI-DI
PegAssist® Insole		PAS0	00609271319059
PegAssist® Insole		PAS1	00609271319158
PegAssist® Insole		PAS2	00609271319257
PegAssist® Insole		PAS3	00609271319356
PegAssist® Insole		PAS4	00609271319455
PegAssist® Insole		PAS-M1	00609271330153
PegAssist® Insole		PAS-M2	00609271330252
PegAssist® Insole		PAS-M3	00609271330351
PegAssist® Insole		PAS-M4	00609271330450
PegAssist® Insole		PAS-W1	00609271333154
PegAssist® Insole		PAS-W2	00609271333253
PegAssist® Insole		PAS-W3	00609271333352
PegAssist® Insole	PQ0		00609271909090
PegAssist® Insole	PQ1		00609271909199
PegAssist® Insole	PQ2		00609271909298
PegAssist® Insole	PQ3		00609271909397
PegAssist® Insole	PQ4		00609271909496
PegAssist® Insole	PTQM1		00609271920194
PegAssist® Insole	PTQM2		00609271920293
PegAssist® Insole	PTQM3		00609271920392
PegAssist® Insole	PTQM4		00609271920491
PegAssist® Insole	PTQW1		00609271923195
PegAssist® Insole	PTQW2		00609271923294
PegAssist® Insole	PTQW3		00609271923393
PegAssist® Insole	PW0		00609271909595
PegAssist® Insole	PW1		00609271909694
PegAssist® Insole	PW2		00609271909793
PegAssist® Insole	PW3		00609271909892
PegAssist® Insole	PW4		00609271909991

Basic-UDI	PQ Series	0609271PQR9
	PTQ Series	0609271PTQDA
	PW Series	0609271PWRM
	PAS Series	0609271PASBM
	PAS- Series	0609271PAS-WJ
GMDN:		41575
EMDN:		Y061203
UMDNS:		17-873

Intended Purpose: The DARCO Peg Assist Offloading Insoles promote healing when used in conjunction with the proper DARCO post-operative or post-trauma healing shoes or walkers to reduce pressure in identified areas on the sole of a patient's foot by means of an adjustable and customizable hexagonal peg 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 3rd day of November, 2021

Signature: Mark S. Cooper