EC Declaration of Conformity

Air Traveler Walker

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
AirTraveler Walker XS	AT0	AT0	00609271989054
AirTraveler Walker S	AT1	AT1	00609271989153
AirTraveler Walker M	AT2	AT2	00609271989252
AirTraveler Walker L	AT3	AT3	00609271989351
AirTraveler Walker XL	AT4	AT4	00609271989450
AirTraveler Walker short XS	ATS0	ATS0	00609271999053
AirTraveler Walker short S	ATS1	ATS1	00609271999152
AirTraveler Walker short M	ATS2	ATS2	00609271999251
AirTraveler Walker short L	ATS3	ATS3	00609271999350
AirTraveler Walker short XL	ATS4	ATS4	00609271999459

Basic-UDI	0609271ATQ2
GMDN:	36206
EMDN:	Y06120601
UMDNS:	17-873

Intended Purpose: The Air Traveler Walker is indicated for the treatment of soft tissue injuries (grade 2 or 3 sprains), stable fractures, post-operative use, trauma, rehab, and any other conditions recommended by a health care professional requiring compression and immobilization of the lower leg. The Air traveler Walker is available in 5 tall and 5 short sizes.

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 19th day of January, 2022.

Signature: Mark S. Cooper