UK Declaration of Conformity

Toe Alignment Splint

Manufacturers Name:	DARCO International, Inc.
Manufacturer's Address:	810 Memorial Boulevard Huntington WV 25701 United States of America
UK Responsible Person Name:	V-M Orthotics LTD
UK Responsible Person Address:	Unit 25, Halesworth Business Centre Norwich Road Halesworth IP19 8QJ United Kingdom

Name of Device	ProductCode US	UDI-DI
Toe Alignment Splint	TAS	00609271039964

Basic-UDI	0609271TASC9
GMDN:	65660
EMDN:	M03050299
UMDNS:	13-369

Intended Purpose: The DARCO Toe Alignment Splint is designed to provide post operative toe alignment after Hallux Valgus, Hammer Toe and Tailor's Bunion procedures.

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 UKCA labelling of its products according to UK MDR 2002 as modified: Class 1: UKCA conformity declaration according to UK MDR 2002, Annex IX (as modified by Schedule 2A to the UK MDR 2002), Section III, Rule 1.

We declare under our sole responsibility that the above listed medical devices according to UK MDR Annex VII (as modified by Schedule 2A to the UK MDR 2002) meet all applicable basic safety and performance requirements.

This declaration is supported by the manufacturers quality management system compliant with ISO 13485:2016 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 Cooper as its Director of Regulatory Affairs on the 9th day of December, 2022.

Signature: Mark Cooper