

C-PRO DIRECT LTD, 7A ENTERPRISE WAY, EDENBRIDGE, KENT, TN8 6HF, ENGLAND

TEL: +44 (0)1732 860 158 EMAIL: enquries@c-prodirect.com WEBSITE: www.c-prodirect.com DECLARATION OF CONFORMITY

Manufacturer:	C-Pro Direct Ltd
	0.100.100.00
Manufacturer Address:	7a Enterprise Way Edenbridge Kent TN8 6HF. United Kingdom
GB Manufacturer Single	GB-MF-000025827
Registration Number (SRN):	
EU Authorised Representative and Importer place of business	C-Pro Direct Ireland Limited, Registered Office: 57 Amiens Street,
	Dublin 1, D01YY11 and operating from Unit 3, Block 1, Port Tunnel
	Business Park, Clonshaugh, Dublin 17, D17PA46
EU Authorised Representative	IE-AR-000019792
Single Registration Number (SRN):	IE-AK-000019792
EU Importer Single Registration	IE INA 000022220
Number (SRN):	IE-IM-000023320
	ADM Modular System Orthopaedic Braces:
Product Name(s):	ADM Abduction Dorsiflexion Mechanism with ADM
, ,	Modular System Side Clip System (Grey)
For a complete definition of	2. ADM Ankle Foot Orthosis (Green / Grey) (Sizes 0000 to 12)
product names, codes and Unique	including Tongues
Device Identifiers (UDIs) at	3. Black Robin Socks
https://c-prodirect.com/mdr-	4. ADM Footwear and Footwear Adaption Kits (Sizes Small,
information	Large, Extra Large)
	5. ADM External Rotation Bars and Clips (Sizes 130mm to
See 093_TECH v013	350mm)
_	6. D-Bar Europe External Rotation Bars
GMDN:	36206 Ankle Foot Orthosis
Basic UDI-DI:	506059152ADMNA35
Product Risk Class:	1
Notified Bodies Used:	Not applicable
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This declaration of conformity has been issued by, and under the sole responsibility of, C-Pro Direct Ltd (Manufacturer). C-Pro Direct Ltd states that the device(s) mentioned herein comply with EU Directive MDR 2017/745 Annex IV for medical devices (includes Annex II and Annex III) and United Kingdom MDR 2002 – (SI 2002 No 618, as amended) declares that. This statement is supported by C-Pro Direct Ltd and C-Pro Direct Ireland Limited ISO 13485 compliant Quality Management System (certificate number DNKFRC102) issued by Bureau Veritas. All supporting document is retained by C-Pro Direct Ltd.

HPRA

7a Enterprise Way, Edenbridge, Kent, TN8 6HF, England.

01 Jun 2021

Mr Philip Morris, B.Eng MIET Director (C-Pro Direct Ltd)

EU Competent Authority:

