

EU & UK DECLARATION OF CONFORMITY

Manufacturer:	C-Pro Direct Ltd
Manufacturer Address:	7a Enterprise Way Edenbridge Kent TN8 6HF
Single Registration Number (SRN):	Not issued
EU Authorised Representative:	C-Pro Direct Ireland Limited
Product Name(s):	ADM Modular System Orthopaedic Braces: <ol style="list-style-type: none"> 1. ADM Abduction Dorsiflexion Mechanism (sizes 3XS to X-L) 2. ADM Ankle Foot Orthosis (Sizes 0000 to 12) 3. ADM Footwear Adaption Kits (Sizes Small, Large, Extra Large) 4. ADM External Rotation Bars and Clips (Sizes 130mm to 350mm) Specification of product codes and GTINs at www.c-prodirect.com
GMDN:	36206 Ankle Foot Orthosis
Basic UDI-DI:	506059152ADMNA35
EU / UK Product Class:	1
Notified Bodies Used:	Not applicable
UK Competent Authority:	MHRA
EU Competent Authority:	HPRA

This declaration of conformity is issued by C-Pro Direct Ltd (Manufacturer). C-Pro Direct Ltd hereby declares the device(s) specified above conform to the EU Regulation MDR 2017/745 for medical devices and the UK MDR 2002 – (SI 2002 No 618, as amended). This declaration is supported by the C-Pro Direct Ltd and C-Pro Direct Ireland Limited ISO 13485 compliant Quality Management System issued by Bureau Veritas (certificate number DNKFRC102). All supporting documentation is retained by C-Pro Direct Ltd.



01 May 2021

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

