

UK DECLARATION OF CONFORMITY

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| Manufacturer | C-Pro Direct Ltd |
| Manufacturer Address: | 7a Enterprise Way Edenbridge Kent TN8 6HF. United Kingdom |
| GB Manufacturer Single Registration Number (SRN): | GB-MF-000025827 |
| MHRA Account No: | 5447 |
| EU Authorised Representative Single Registration Number (SRN): | IE-AR-000019792 |
| EU Importer Single Registration Number (SRN): | IE-IM-000023320 |
| Product Name: | ADM Modular Brace System The ADM Modular Brace System Comprises numerous specific devices, each with a Unique Device Identifier. See Appendix A overleaf for further details |
| Intended use: | Prevention of clubfoot relapse and or supinated gait. Management of Vertical Talus and Metatarsus Adductus. Use as directed by clinician |
| GMDN: EMDN: | 36206 Ankle Foot Orthosis Y061206 Orthosis, Ankle Foot |
| Basic UDI-DI: | 506059152ADMNA35 |
| Product Risk Class: | 1 |
| Notified Bodies Used: | Not applicable |
| EU Competent Authority: | HPRA |
| Standards applied: | ISO 13485 Medical Devices, ISO 14971:2019 Medical Device Risk Management, ISO 24971:2020 Guidance on the application of ISO 14971, ISO 15223-1 2021 Medical Device Symbols to be used, 20417: 2021 Information to be supplied by the manufacturer, ISO 10993-1 Biological Evaluation of Medical Devices (material toxicity), ISO 14001:2015 Environmental Management Systems |

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 with United Kingdom MDR 2002 – (SI 2002 No 618, as amended). This statement is supported by C-Pro Direct Ltd and C-Pro Direct Ireland Limited ISO 13485 compliant Quality Management System (certificate number DNKFRC102242) issued by Bureau Veritas (expire 01 July 2026). All supporting document is retained by C-Pro Direct Ltd.



7a Enterprise Way, Edenbridge, Kent, TN8 6HF, England.
 04 April 2024

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



EU DECLARATION OF CONFORMITY

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Appendix A: Further Device Details

ADM Modular Brace System

The ADM Modular Brace System Comprises numerous specific devices, each with a Unique Device Identifier. The devices fall into a range of Categories as listed below that are further defined by the C-Pro Direct spreadsheet referenced 093_TECH v017 which is available at www.c-prodirect.com

1. ADM Sandals / AFOs: Night use Ankle Foot Orthosis (AFO) for prevention of clubfoot relapse when used ADM Modular Brace System configurations (093_TECH Category 30)
2. ADM: Abduction Dorsiflexion Mechanism (093_TECH Category 31)
3. ADM (X-L size): Abduction Dorsiflexion Mechanisms in the XL size for use on feet sized between 220mm and 270mm in length (093_TECH Category 33)
4. ADM External Rotation Bars: External Rotation Bars for use as a foot abduction brace (093_TECH Category 32)
5. ADM Bar Clips: Used with ADM External Rotation Bars to form a Clubfoot External Rotation Brace (aka Denis Browne Brace) (093_TECH Category 35)
6. Spring Assisted Articulating Bar Clips: A variant of ADM Bar Clips that can be used with ADM External Rotation Braces to creates an Articulating External Rotation Bar (aka Dobbs Brace) (093_TECH Category 36)
7. D-Bar Europe: Articulating External Rotation Bar (aka Dobbs Braces) for use with Mitchell, Markell and IOWA clubfoot brace systems (093_TECH Category 28)
8. ADM Footwear: Adapted footwear for use as braces as part of the ADM Modular Brace System (093_TECH Category 16)
9. ADM Sole Kts: Kits to enable Orthopaedic workshops / persons skilled in the craft to adapt or make footwear that can be used as part of the ADM Modular Brace System (093_TECH Category 36)
10. Black Robin Socks: Accessories to the ADM Modular Brace System AFO products recommended to protect skin and promote good foot health (093_TECH Category 5)
11. Fitting Stock: Collections of ADMs Bars and Clips in an easy to use dispensing box and AFO liners for determination of patient foot size (093_TECH Category 17)
12. ADM Strap Pads: Accessories to the ADM Sandals / AFO. Strap Pads are supplied with all ADM AFOs, but are also available separately as spares (093_TECH Category 19)