c-prodirect
Proud to support the Ponseti method

UK DECLARATION OF CONFORMITY

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

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: Product code: UDI:	Dorsi Ramp DORSI 5060591512578
Intended use:	Physiotherapy aid to stetching of the achilles tendon in patients up to the age of 10 years
GMDN: EMDN:	63490 Paediatric Slant Board Z120602 Physiotherapy Equipment
Basic UDI-DI:	506059152ADMNA35
Product Risk Class:	1
Notified Bodies Used:	Not applicable
UK Competent Authority:	MHRA
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 UKAS 212776 (expires 01 July 2026). All supporting documentation is retained by C-Pro Direct Ltd.

7a Enterprise Way, Edenbridge, Kent, TN8 6HF, England.
17 October 2024

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

UK CA