

Introduction

This document details C-Pro Direct labelling of Medical Device products

Definitions:

Product Packaging: Product Packaging for Medical Device products will always have an MDR compliant label attached at the time of manufacture. Product Packaging may be a sealed carton, poly bag or bubble wrap bag depending on the item.

Product Carton: Is a further level of packaging beyond Product Packaging used to store one or a multiple number of products. Product Cartons are used where necessary to facilitate transportation and storage

Despatch Label (formally called Stock Label): This label is applied to Product Packaging and / or Product Cartons as part of the despatch process (106_PRO). In addition to basic product identification data Despatch labels also carry details of the customer order and order references for each order line item. Despatch may therefore only be applied at despatch time in the context of a specific sales order. Despatch labels are generated using Bartender Software which reads from the Sage accounting system database.

Shipping Carton: Is the outermost carton, bag, envelope used for transportation of the products to their destination. The courier's Courier Waybill is applied to the Shipping Carton.

Wasp label: Is a label generated by the C-Pro Direct stock control system. The Wasp label is machine readable and carries Item, Lot and Date Code (expiry date) information

GS1 Data Matrix: Is a two dimensional barcode format used for Medical Device labelling. GS1 Data Matrix labels enable multiple data items (e.g., Unique Device Identification data and Production Information – UDI-PI) to be encoded and read by devices with GS1 Matrix Parsing capability.

Code 128 (Linear barcode): Is a one dimensional barcode format that is machine readable and used on medical device labelling

Product Packaging Medical Device Labelling

Standard format used for most C-Pro Direct products (100mm x 50mm)

Label attached to
Product Packaging

**Main label attached to
packaging**

GS1
Data
Matrix



GTIN (01) 5 0562930 099110
Expiry date (YYMMDD) 09/06/2021
Lot Number (17) 250609
LOT (10) 90621
C-Pro product code (240) 9090BXXXSLN

Product Description

90STJ 90TTJ BLUE XXX-SMALL LEFT ADM,
NON-AMBULATORY

Date of manufacture



09/06/2021

Rev: MDv004

Revision



C-Pro Direct Ltd. UK. TN8 6HF



C-Pro Direct Ireland Ltd. Dublin. D06124

Manufacturer / EU Representative

**Mini label attached to product when larger
label attachment is not possible**

9090BXXXSLN
250521
250525

C-Pro product code

Lot Number

Expiry date (YYMMDD)

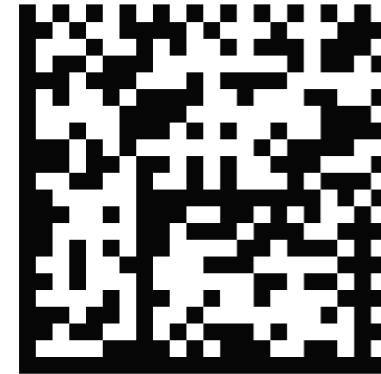
Product Packaging Medical Device Labelling

Alternative Format #1 (50.8mm 76.2mm)


This format is used
for Grey / Green EVA
AFOs in pairs


SIZE 0000

ADM ANKLE FOOT
ORTHOSIS (1 PAIR)
CLASS 1 MEDICAL
DEVICE



GTIN (01) 5 0562930 05937 4

 (17) 250530

 **LOT** (10) 210530

(240) 0000GGLREVA



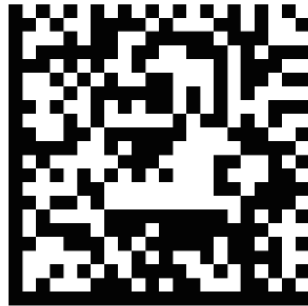
C-PRO DIRECT LTD, EDENBRIDGE, KENT, UNITED KINGDOM




C-PRO DIRECT IRELAND LIMITED, DUBLIN, IRELAND

**Product Packaging
Medical Device Labelling**


Alternative Format #2 (50.8mm 76.2mm)




 C-Pro Direct Ltd. UK. TN8 6HF

 C-Pro Direct Ireland Ltd.
Dublin. D06124

GTIN (01) 5 0605915 18105 6

 28/10/2020

 (17) 241028





LOT (10) 27865
(240) 0BLA

**SANDAL BLUE SIZE 0
LEFT, ADM**

Product Packaging Medical Device Labelling

Alternative Format #3

This format is used for Dorsi Ramps manufactured prior to the MDR enforcement date

| | | |
|---|-------------------|------------------|
|  | Manufacturer: | C-Pro Direct Ltd |
|  | Catalogue No: | DORSIRAMP |
|  | Lot number: | CPD004R102 |
|  | Manufacture date: | September 2018 |

C-Pro Direct Ltd, 7a Enterprise Way, Edenbridge,
Kent. TN8 6HF. UK



Despatch Label

This label is attached to Product Packaging and / or Product Cartons at time of despatch to provide customers with order / patient details

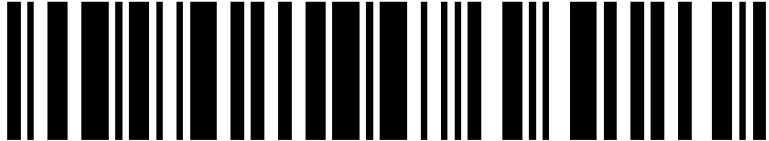
SANDAL PINK SIZE 1 LEFT ← Product description

Cust Ref: X815306 ← Customer's ref

Order No: 100325 ← Sales Order number

Line No: 1 ← Sales Order line number

Stock Code: 1PL ← Product code

 ← GTIN / UDI

(8100) 608843 (93)

C-Pro Direct Ltd, 7a Enterprise Way, Edenbridge Kent,
UK. TN8 6HF. Enquiries@c-prodirect.com ← Despatch site address (UK address shown)

Wasp Label

This label is attached to Product Packaging and / or Product Cartons for internal movement control



Note: C-Pro Direct policy is to reduce the number of labels on packaging. When our stock management system software fully supports GS1 Data Matrix Parsing the use of Wasp labels will be reduced.