



DECLARATION OF CONFORMITY

Manufacturer:

HMP Enterprises Inc,
125 Carnes Drive
Fayetteville
GA 30214
USA

SRN:

Not known

EU Authorised Representative:

Eurolink Europe Compliance Limited
25 Herbert Place
Dublin
D02 AY86
Republic of Ireland

SRN:

IE-AR-000002852

We the undersigned certify and declare under our sole responsibility that the following apparatus

Conforming Apparatus:

Dry Pro™ PICC Protector
Dry Pro™ Arm and Leg Cast Protector
Dry Pro™ Prosthetic Protector
Dry Pro™ Ostomy Protector

Device Name and UDI-DI Numbers:

See Page 2 below

Basic UDI-DI:

Not known

Risk Class:

MDR Annex VIII Rule 1

Health Products Regulatory Authority Registration Reference:

MDROEO202003251341_5

Technical Document Reference No:

TF-0001

Common Specifications

EN ISO 14971:2019 Medical Devices – Application of
Risk Management to Medical Devices

Medical Devices Regulations – Annex I, General
Requirements

conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 5 April 2017 on medical devices

Signed:

Graham White – Operations
Manager

Date:

31 January 2023

Issued:

Dublin, Ireland

Device Name	UDI-DI/GTIN
Cast and Wound Cover, Small Half Arm	673034021138
Cast and Wound Cover, Large Half Arm	673034021152
Cast and Wound Cover, X-Small Full Arm	673034041129
Cast and Wound Cover, Small Full Arm	673034041143
Cast and Wound Cover, Medium Full Arm	673034041167
Cast and Wound Cover, Large Full Arm	673034041181
Cast and Wound Cover, Small Half Leg	673034022135
Cast and Wound Cover, Large Half Leg	673034022159
Cast and Wound Cover, X-Small Full Leg	673034042126
Cast and Wound Cover, Small Full Leg	673034042140
Cast and Wound Cover, Medium Full Leg	673034042164
Cast and Wound Cover, Large Full Leg	673034042188
PICC IV Line and Wound Cover, X-Small	673034099113
PICC IV Line and Wound Cover, Small	673034099137
PICC IV Line and Wound Cover, Medium	673034099151
PICC IV Line and Wound Cover, Large	673034099175
PICC IV Line and Wound Cover, X-Large	673034099199
Ostomy and Wound Cover, X-Small	673034075124
Ostomy and Wound Cover, Small	673034075148
Ostomy and Wound Cover, Medium	673034075162
Ostomy and Wound Cover, Large	673034075186
Ostomy and Wound Cover, X-Large	673034075209
Waterproof Prosthetic Cover, X-Small	673034052118
Waterproof Prosthetic Cover, Small	673034052132
Waterproof Prosthetic Cover, Medium	673034052156
Waterproof Prosthetic Cover, Large	673034052170
Waterproof Prosthetic Cover, X-Large	673034052184