


Device: Shower Protectors	UK & EU DECLARATION OF CONFORMITY		
	REF: TF05-1.10		
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UK & EU DECLARATION OF CONFORMITY

Under our sole responsibility, we declare that the medical devices known as the Independence & DialTec Waterproof Wound Protection Pouches (Shower Protectors), are for transient use, described hereafter as Class I (in accordance with the Risk Class - Rule 1) and is in conformity with the Annex I for the General Safety & Performance Requirements; and provisions of EU Medical Devices Regulation 2017/745 and is subject to the procedure set out in Article 19 of that Regulation; along with the UK Medical Devices Regulations 2002.

It is manufactured in accordance with the Procedures and Policies contained in our Quality Management System, which has been registered with International Associates Ltd against the international Standard ISO 13485:2016.

UMDNS Number:	17583 - Water Proofing Protectors
GMDN Number:	33536 - Cover, cast / bandage, waterproof
EMDN:	M0499 – Special Dressings
UNSPSC:	42310000 – Wound Care Products
CND:	Y09399 – Devices for Showering
Independence Product Codes:	VAP1/VAP2/VAP3
DialTec Product Codes:	DTSP1/DTSP2/DTSP0
Independence Basic UDI DI:	506102572VAPDF
DialTec Basic UDI DI:	506102572DTSP6C
ISO Certificate Number:	01-1147-1-MED
UKAS Number:	10093
Company Registration:	05929050
NBOG Number:	MD0100
MDN:	1204 – Wound & Skin Care
MDT:	2002 – Plastic Processing
NBOG Number:	MD0100 - General Non-Active, Non Implantable

Signed By



Management Representative

24th June 2023



Independence Products Ltd, Unit 7j Blenheim Court Blenheim Park Road, Blenheim Industrial Estate, Bulwell, Nottingham, England, NG6 8YP			
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NBOG - Notified Body Operations Group	ISO – International Organisation for Standardization	MDCG – Medical Device Coordination Group	MHRA – Medicines & Healthcare Products Regulatory Agency
EMDN – European Medical Devices Nomenclature			
UNSPSC - United Nations Standard Products and Services Code	CND – National Classification of Medical Devices	UMDNS – Universal Medical Devices Nomenclature System	GMDN – Global Medical Devices Nomenclature
MDN – Medical Devices Non-Active	MDT – Medical Devices Technologies	UKAS – United Kingdom Accreditation Service	UDI – Unique Device Indicator