

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Promedics Orthopaedics Ltd.	Port Glasgow Industrial Estate, Gareloch Road, Port Glasgow, Scotland, UK, PA14 5XH	GB-MF-000008558

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION			
Generic Device Group (GDG)			
B4 Spinal & Cervical			
Product Name	Product Code / Catalog Number	Basic UDI-DI	
Abdominal Support Lumbosacral Support (LSO) Thoracolumbosacral Support (TLSO) Two piece Cervical collar with chin support and tracheotomy opening Cervico-thoracic Orthosis (CTO)	See attached list	50554741B47P	
Intended Purpose			
For adult and paediatric treatment of Spinal/Cervical injury or ailment. For use in hospital, home or work environment for support, pain relief, and stability.			

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class I Rule 1	None

Promedics Orthopaedics Ltd declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE: Steve Duxbury

TITLE: Technical Manager & PRRC

SIGNATURE:



PLACE: Port Glasgow

DATE: 06-10-2021

REF	Description	UDI
140891	VELPEAU ABDOMINAL CLASSIC 1	4063591222240
140892	VELPEAU ABDOMINAL CLASSIC SIZE 2	4063591222301
140893	VELPEAU ABDOMINAL CLASSIC SIZE 3	4063591222325
ABH/L	AB HEALER LARGE	5056356209814
ABH/M	AB HEALER MEDIUM	5056356209821
ABH/S	AB HEALER SMALL	5056356209838
ABH/XL	AB HEALER X LARGE	5056356209845
ABH/XS	AB HEALER EXTRA SMALL	5056356209852
ABH/XXL	AB HEALER XX LARGE	5056356209869
BULK034-L	WHITE ABDOMINAL SUPPORT LARGE 20CM	5056356223414
BULK034-L2	WHITE ABDOMINAL SUPPORT LARGE 25CM	5056356223438
BULK034-L3	WHITE ABDOMINAL SUPPORT LARGE 30CM	5056356223421
BULK034-M	WHITE ABDOMINAL SUPPORT MEDIUM 20CM	5056356223445
BULK034-M2	WHITE ABDOMINAL SUPPORT MEDIUM 25CM	5056356223469
BULK034-M3	WHITE ABDOMINAL SUPPORT MEDIUM 30CM	5056356223452
BULK034-S	WHITE ABDOMINAL SUPPORT SMALL 20CM	5056356223476
BULK034-S2	WHITE ABDOMINAL SUPPORT SMALL 25CM	5056356223483
BULK034-S3	WHITE ABDOMINAL SUPPORT SMALL 30CM	5056356223506
BULK034-XL	WHITE ABDOMINAL SUPPORT X LARGE 20CM	5056356223490
BULK034-XL2	WHITE ABDOMINAL SUPPORT X LARGE 25CM	5056356223582
BULK034-XL3	WHITE ABDOMINAL SUPPORT X LARGE 30CM	5056356223513
BULK034-XXL2	WHITE ABDOMINAL SUPPORT XX LARGE 25CM	5056356223520
GENI-S-RBB	GENI MEDICAL RIB BELT MALE	5056356231327
GENI-S-RBB/F	GENI MEDICAL RIB BELT FEMALE	5056356231334
PCC/33	SMALL 3 1/4" TRACHEA PHILLY COLLAR	5055474153405
PCC/34	SMALL 4 1/4" TRACHEA PHILLY COLLAR	5055474153412
PCC/35	SMALL 5 1/4" TRACHEA PHILLY COLLAR	5055474153429
PCC/53	MEDIUM 3 1/4" TRACHEA PHILLY COLLAR	5055474153436
PCC/54	MEDIUM 4 1/4" TRACHEA PHILLY COLLAR	5055474153443
PCC/55	MEDIUM 5 1/4" TRACHEA PHILLY COLLAR	5055474153450
PCC/73	LARGE 3 1/4" TRACHEA PHILLY COLLAR	5055474153474
PCC/74	LARGE 4 1/4" TRACHEA PHILLY COLLAR	5055474153481
PCC/75	LARGE 5 1/4" TRACHEA PHILLY COLLAR	5055474153498
UTP/10	UNIVERSAL TWO PIECE COLLAR	5056356279770
BC/1	BUDGET COLLAR SMALL	5055474112228
BC/2	BUDGET COLLAR MEDIUM	5055474112235
BC/3	BUDGET COLLAR LARGE	5055474103974
BC/4	BUDGET COLLAR LARGE/DEEP	5055474112242
FC/1	HALTON COLLAR LARGE	5055474116707
FC/2	HALTON COLLAR MEDIUM	5055474116714
FC/3	HALTON COLLAR SMALL	5055474116721
FC/4	HALTON COLLAR LONG/MEDIUM	5055474116738
FC/5	HALTON COLLAR MEDIUM/MEDIUM	5055474116745
FC/6	HALTON COLLAR LONG/SHALLOW	5055474116752
FC/7	HALTON COLLAR MEDIUM/SHALLOW	5055474116769
FC/8	HALTON COLLAR X SMALL	5055474116776
JBC/1	PAEDIATRIC SOFT FOAM COLLAR SMALL	5055474119968
JBC/2	PAEDIATRIC SOFT FOAM COLLAR MEDIUM	5055474119975
JBC/3	PAEDIATRIC SOFT FOAM COLLAR LARGE	5055474119982
MBAS/1	MATERNITY BELT STYLE A SIZE 1	5055474132318

REF	Description	UDI
MBAS/2	MATERNITY BELT STYLE A SIZE 2	5055474132332
MBAS/3	MATERNITY BELT STYLE A SIZE 3	5055474132608
MBAS/4	MATERNITY BELT STYLE A SIZE 4	5055474132622
MBAS/5	MATERNITY BELT STYLE A SIZE 5	5055474132646
MBAS/6	MATERNITY BELT STYLE A SIZE 6	5055474132660
MBAS/7	MATERNITY BELT STYLE A SIZE 7	5055474132684
MBAS/8	MATERNITY BELT STYLE A SIZE 8	5055474132707
MBAS/9	MATERNITY BELT STYLE A SIZE 9	5055474132721
MBB/1	MATERNITY BELT STYLE B SIZE 1	5055474132738
MBB/10	MATERNITY BELT STYLE B SIZE 10	5055474189497
MBB/11	MATERNITY BELT STYLE B SIZE 11	5056356279961
MBB/12	MATERNITY BELT STYLE B SIZE 12	5055474132752
MBB/2	MATERNITY BELT STYLE B SIZE 2	5055474130512
MBB/2/BK	MATERNITY BELT STYLE B SIZE 2 - BLACK	5055474132769
MBB/3	MATERNITY BELT STYLE B SIZE 3	5055474132776
MBB/3/BK	MATERNITY BELT STYLE B SIZE 3 - BLACK	5055474132783
MBB/4	MATERNITY BELT STYLE B SIZE 4	5055474130529
MBB/4/BK	MATERNITY BELT STYLE B SIZE 4 - BLACK	5055474132790
MBB/5	MATERNITY BELT STYLE B SIZE 5	5055474130536
MBB/5/BK	MATERNITY BELT STYLE B SIZE 5 - BLACK	5055474132806
MBB/6	MATERNITY BELT STYLE B SIZE 6	5055474130543
MBB/6/BK	MATERNITY BELT STYLE B SIZE 6 - BLACK	5055474132813
MBB/7	MATERNITY BELT STYLE B SIZE 7	5055474130550
MBB/7/BK	MATERNITY BELT STYLE B SIZE 7 - BLACK	5055474132820
MBB/8	MATERNITY BELT STYLE B SIZE 8	5055474130567
MBB/8/BK	MATERNITY BELT STYLE B SIZE 8 - BLACK	5055474132837
MBB/9	MATERNITY BELT STYLE B SIZE 9	5055474130574
MBB/9/BK	MATERNITY BELT STYLE B SIZE 9 - BLACK	5056356279978
PCC/32	SMALL 2 1/4" TRACHEA PHILLY COLLAR	5055474153399
PCC/52	MEDIUM 2 1/4" TRACHEA PHILLY COLLAR	5055474170112
PCC/72	LARGE 2 1/4" TRACHEA PHILLY COLLAR	5055474153467
PF/83	PROFLEX BELT WITH FLEXI PANEL 8" SMALL	5055474153733
PF/85	PROFLEX BELT WITH FLEXI PANEL 8" MEDIUM	5055474153740
PF/87	PROFLEX BELT WITH FLEXI PANEL 8" LARGE	5055474153757
PF/88	PROFLEX BELT WITH FLEXI PANEL 8" X LARGE	5055474153764
PF/89	PROFLEX BELT WITH FLEXI PANEL 8" XXLARGE	5055474153771
PFM/83	PROFORM BELT SMALL	5055474154051
PFM/85	PROFORM BELT MEDIUM	5055474154068
PFM/87	PROFORM BELT LARGE	5055474154075
PFM/88	PROFORM BELT X LARGE	5055474154082
PFM/89	PROFORM BELT XX LARGE	5055474154099
PFM/XXXL	PROFORM BELT XXX LARGE	5055474154105
SPD/1	PELVIC SUPPORT BELT SIZE 1	5055474105428
SPD/1/BK	PELVIC SUPPORT BELT SIZE 1 - BLACK	5055474192039
SPD/2	PELVIC SUPPORT BELT SIZE 2	5055474105435
SPD/2/BK	PELVIC SUPPORT BELT SIZE 2 - BLACK	5055474192053
SPD/3	PELVIC SUPPORT BELT SIZE 3	5055474105442
SPD/3/BK	PELVIC SUPPORT BELT SIZE 3 - BLACK	5055474192077
SPD/4	PELVIC SUPPORT BELT SIZE 4	5055474105459
SPD/4/BK	PELVIC SUPPORT BELT SIZE 4 - BLACK	5055474192091

REF	Description	UDI
SPD/5	PELVIC SUPPORT BELT SIZE 5	5055474105466
SPD/5/BK	PELVIC SUPPORT BELT SIZE 5 - BLACK	5055474192114
SPD/6	PELVIC SUPPORT BELT SIZE 6	5055474105473
SPD/6/BK	PELVIC SUPPORT BELT SIZE 6 - BLACK	5055474192138
SPD/7	PELVIC SUPPORT BELT SIZE 7	5055474105480
SPD/7/BK	PELVIC SUPPORT BELT SIZE 7- BLACK	5055474192152
SPD/8	PELVIC SUPPORT BELT SIZE 8	5055474105497
SPD/8/BK	PELVIC SUPPORT BELT SIZE 8 - BLACK	5055474192176
TB/01	PRO TEM BELT XX SMALL	5055474165125
TB/02	PRO TEM BELT X SMALL	5055474165132
TB/03	PRO TEM BELT SMALL	5055474165149
TB/05	PRO TEM BELT MEDIUM	5055474165156
TB/07	PRO TEM BELT LARGE	5055474105503
TB/08	PRO TEM BELT X LARGE	5055474130758
TB/09	PRO TEM BELT XX LARGE	5055474130765
TB/10	PRO TEM BELT XXX LARGE	5055474165163
TO1303N/L	HYPEREXTENSION BRACE - LARGE	5056356279800
TO1303N/M	HYPEREXTENSION BRACE - MEDIUM	5056356279817
TO1303N/S	HYPEREXTENSION BRACE - SMALL	5056356280813
TO1303N/XL	HYPEREXTENSION BRACE - X LARGE	5056356279824
TO1303N/XS	HYPEREXTENSION BRACE - X SMALL	5056356279831
TO1303N/XXL	HYPEREXTENSION BRACE - XX LARGE	5056356279848
WMB/1	WILTSHIRE MATERNITY BELT SIZE 1	5055474166658
WMB/1/BK	WILTSHIRE MATERNITY BELT SIZE 1 BLACK	5055474166665
WMB/2	WILTSHIRE MATERNITY BELT SIZE 2	5055474166672
WMB/2/BK	WILTSHIRE MATERNITY BELT SIZE 2 BLACK	5055474166689
WMB/3	WILTSHIRE MATERNITY BELT SIZE 3	5055474166696
WMB/3/BK	WILTSHIRE MATERNITY BELT SIZE 3 BLACK	5055474166702
WMB/4	WILTSHIRE MATERNITY BELT SIZE 4	5055474166719
WMB/4/BK	WILTSHIRE MATERNITY BELT SIZE 4 BLACK	5055474166726