

# 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)			
B3 Upper Limb			
Product Name	Product Code / Catalog Number	Basic UDI-DI	
Arm Immobiliser Trauma Slings Arm Elevation Slings Clavicle Brace Cubital Tunnel Splint Tennis Elbow Brace Elbow Post Op ROM Elbow Wraps" Shoulder Immobiliser Shoulder Abduction Sling Subluxation Cuff Shoulder Supports / Stabliser	See attached list	50554741B37M	
Intended Purpose			
For adult and paediatric treatment of Arm & Shoulder injury or ailment. Alleviation of post-operative & post trauma pain arising from arthroscopic procedure, reconstructive procedure, general surgery and physical therapy. For use in hospital, home or work environment for support, pain relief, stability or post- operative care.			

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:** 17 October 2022

REF	Description	UDI
137480	VELPEAU CLAVICLE CLASSIC T1	4056649685760
137487	CELLACARE GILCHRIST CLASSIC FBDGE GR3	4056649685968
137488	CELLACARE GILCHRIST CLASSIC FBDGE GR4	4056649685982
137481	VELPEAU CLAVICLE CLASSIC T2	4056649685869
137485	CELLACARE GILCHRIST CLASSIC FBDGE GR1	4056649685883
137486	CELLACARE GILCHRIST CLASSIC FBDGE GR2	4056649685944
137490	CELLACARE CLAVICLE CLASSIC FBDGE GR1	4056649686002
137491	CELLACARE CLAVICLE CLASSIC FBDGE GR2	4056649686026
4096-07	AXELLÅS TVÅDELAD LARGE	5050996020327
4096-05	AXELLÅS TVÅDELAD MEDIUM	5050996020334
4096-03	AXELLÅS TVÅDELAD SMALL	5050996020341
4096-08	AXELLÅS TVÅDELAD X LARGE	5050996020358
4097-07	AXELLÅS LARGE	5050996020365
4097-05	AXELLÅS MEDIUM	5050996020372
4097-03	AXELLÅS SMALL	5050996020389
ASCE/L/REG	ASCENDER TELESCOPIC ELBOW BRACE REG LEFT	5055474198888
ASCE/R/REG	ASCENDER TELESCOPIC ELBOW BRACE REG RIGHT	5055474198895
BMC-JSIL	SHOULDER IMMOBILISER MITELLA LARGE (10)	5056420602329
BMC-JSIM	SHOULDER IMMOBILISER MITELLA MEDIUM (10)	5056420602312
BMC-JSIS	SHOULDER IMMOBILISER MITELLA SMALL (10)	5056420602305
BMC-JSIXL	SHOULDER IMMOBILISER MITELLA XLARGE (10)	5056420602336
BULK021-B	BLUE TENNIS ELBOW UNIVERSAL	5056356223193
BULK028	STRAP ARM SLING	5056356223209
JSI/02	JURA SHOULDER IMMOBILISER X SMALL	5055474159131
JSI/03	JURA SHOULDER IMMOBILISER SMALL	5055474159117
JSI/05	JURA SHOULDER IMMOBILISER MEDIUM	5055474159100
JSI/07	JURA SHOULDER IMMOBILISER LARGE	5055474159094
JSI/08	JURA SHOULDER IMMOBILISER X LARGE	5055474159124
JSL/10	JURA SHOULDER LOCK SLING	5055474151944
LSS/10	LANCASTER SHOULDER SLING	5055474127758
TAU/10	TRAUMA SLING UNIVERSAL ADULT	5055474139423
TEY-ASCE/L/REG	ASCENDER TELESCOPIC ELBOW BRACE REG LFT	5056420601841
TEY-ASCE/R/REG	ASCENDER TELESCOPIC ELBOW BRACE REG RGT	5056420601858
UPS/10	UNIVERSAL PRO-SLING (10 PER BOX)	5055474166078
ASCE/L/REG/SUP	Ascender Telescopic ROM Elbow Orthosis + SUP, Left	5056420600790
ASCE/R/REG/SUP	Ascender Telescopic ROM Elbow Orthosis + SUP, Right	5056420600806
BOS/03	BOSCOMBE SLING SMALL	5055474112945
BOS/05	BOSCOMBE SLING MEDIUM	5055474112952
BOS/07	BOSCOMBE SLING LARGE	5055474112969
BOS/08	BOSCOMBE SLING X LARGE	5055474168300
CTS/10	CUBITAL TUNNEL SPLINT - UNIVERSAL	5055474138815
EAS	EVANS ABDUCTION SLING	5055474104070
ESI/02	ECONOMY SHOULDER IMMOBILISER X SMALL	5055474116066
ESI/03	ECONOMY SHOULDER IMMOBILISER SMALL	5055474116073
ESI/05	ECONOMY SHOULDER IMMOBILISER MEDIUM	5055474116080
ESI/07	ECONOMY SHOULDER IMMOBILISER LARGE	5055474116097
ESI/08	ECONOMY SHOULDER IMMOBILISER X LARGE	5055474186304

REF	Description	UDI
JASS/03	ABDUCTION SHOULDER SLING SUPPORT SMALL	5055474119913
JASS/05	ABDUCTION SHOULDER SLING SUPPORT MEDIUM	5055474119920
JASS/07	ABDUCTION SHOULDER SLING SUPPORT LARGE	5055474119937
JASS/08	ABDUCTION SHOULDER SLING SUPPORT X LARGE	5056356279923
JASSP/10	ABDUCTION SHOULDER PLUS (45° WEDGE)	5055474151913
JCS/10	JURA CALVICLE BRACE - UNIVERSAL	5055474163268
JRC/02	JURA CLASP EXTRA SMALL ONE LINER	5055474122678
JRC/03	JURA CLASP SMALL ONE LINER	5055474122685
JRC/05	JURA CLASP MEDIUM ONE LINER	5055474122692
JRC/07	JURA CLASP LARGE ONE LINER	5055474122708
JRC/08	JURA CLASP EXTRA LARGE ONE LINER	5055474122715
JUC/02	EPICONDYLITIS CLASP - EXTRA SMALL	5055474112433
JUC/03	EPICONDYLITIS CLASP - SMALL	5055474112426
JUC/05	EPICONDYLITIS CLASP - MEDIUM	5055474112402
JUC/07	EPICONDYLITIS CLASP - LARGE	5055474112419
JUC/08	EPICONDYLITIS CLASP - EXTRA LARGE	5060189747221
JUCS/L	EPICONDYLITIS CLASP L 1 SILICONE LINER	5056356277103
JUCS/M	EPICONDYLITIS CLASP M 1 SILICONE LINER	5056356277110
JUCS/S	EPICONDYLITIS CLASP S 1 SILICONE LINER	5056356277127
JUCS/XL	EPICONDYLITIS CLASP XL 1 SILICONE LINER	5056356277134
JUCS/XS	EPICONDYLITIS CLASP XS 1 SILICONE LINER	5056356277141
JUC/02/P	EPICONDYLITIS CLASP X S PLAIN LINER	5060189747542
JUC/03/P	EPICONDYLITIS CLASP S PLAIN LINER	5060189747559
JUC/05/P	EPICONDYLITIS CLASP M PLAIN LINER	5060189747566
JUC/07/P	EPICONDYLITIS CLASP L PLAIN LINER	5060189747573
JUC/08/P	EPICONDYLITIS CLASP X L PLAIN LINER	5060189747580
LSS/10-B	LANCASTER SHOULDER SLING BIAS BOUND	5055474127765
LSS/10BLK	LANCASTER SHOULDER SLING - BLACK	5055474189282
LSS/25	LANCASTER SHOULDER SLING BOX OF 25	5055474127772
LSS/E/10	LANCASTER SHOULDER SLING 12.5CM LONGER	5055474127789
LSSB/10	LANCASTER SHOULDER BRACE (BABY)	5055474127796
LSSP/10	LANCASTER SHOULDER BRACE (PAEDIATRIC)	5055474152828
PAS/L	PAEDIATRIC ARM SLING - LARGE	5056356208145
PAS/M	PAEDIATRIC ARM SLING - MEDIUM	5056356208138
PAS/S	PAEDIATRIC ARM SLING - SMALL	5056356208121
PAS/XS	PAEDIATRIC ARM SLING - X SMALL	5056356208114
SCF/03	SUBLUXATION CUFF SMALL	5055474158073
SCF/05	SUBLUXATION CUFF MEDIUM	5055474158080
SCF/07	SUBLUXATION CUFF LARGE	5055474158097
SCF/08	SUBLUXATION CUFF XLARGE	5056356279954
SS	SLING STRAP (2 X 12MTRS)	5055474164760
SS/5.5	BLUE SLING STRAP 5.5CM X 12 METRES	5055474172543
TEP/1	UNIVERSAL TENNIS ELBOW STRAP (1 SINGLE)	5056420602954
TEP/10	TENNIS ELBOW STRAP	5055474165170



**Title** Declaration of Conformity: Upper Limb  
**Ref** B3DOC  
**Rev** 8

**Owner** Technical Manager  
**Date** October 2022  
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REF	Description	UDI
VPS/02	VARI PAD TENNIS ELBOW SUPPORT X SMALL	5055474166351
VPS/03	VARI PAD TENNIS ELBOW SUPPORT SMALL	5055474130840
VPS/05	VARI PAD TENNIS ELBOW SUPPORT MEDIUM	5055474105527
VPS/07	VARI PAD TENNIS ELBOW SUPPORT LARGE	5055474105534
VPS/08	VARI PAD TENNIS ELBOW SUPPORT X LARGE	5055474105541
160100	VELPEAU EpEASY CLASSIC 1	4063591667478
160101	VELPEAU EpEASY CLASSIC 2	4063591667515
160102	VELPEAU EpEASY CLASSIC 3	4063591667546