



Positioning Products b.v.

EC Declaration of Conformity
According Council Directive (EU) 2017/745 of the European Parliament and
Council.
Medical Device Regulations

Manufacturer Name:	Positioning Products B.V.
Manufacturer Address:	Veerpolder 1D 2361KV Warmond The Netherland
SRN (single registration number):	NL-IM-000003917
Basic UDI-DI:	872058986008720UZ
Name of the devices:	Chest-, Pelvis- and Ankle Positioning Products as listed in Appendix 1
Product codes:	As listed in Appendix 1
Classification:	Class 1
Conformity assessment route:	Positioning Products B.V. uses the following procedures for CE-labelling for their products according to the regulation MDR 2017/745: Class 1: EC conformity declaration according to Annex II + annex III.

The devices are a multi-use, non-sterile product.

This declaration is issued under the sole responsibility of Positioning Products B.V.

We hereby declare that the medical device specified above meet the provision of the regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer and is designed and produced in accordance with (EU) Medical Device Regulation 2017/745.

Place and date of issue:

Warmond, February 23rd 2022

Issued by: Gerhard van Geest
Partner

Signature:

Appendix 1 Product List

Artikel Code	Omschrijving	GTIN
1.7001.0	Contrabelts 25mm siderelease	08720589860001
1.7002.0	Contrabelts 40mm siderelease	08720589860018
10003	KB_Rack_pack small / Grey	08720589860025
3001	Shower belt / S	08720589860032
3002	Shower belt / M	08720589860049
3003	Shower belt / L	08720589860056
4001	Chest Belt V1 / S	08720589860063
4003	Chest Belt V1 / L	08720589860070
4020	Neoprene Chest Belt X / XS	08720589860087
4021	Neoprene Chest Belt X / S	08720589860094
4022	Neoprene Chest Belt X / M	08720589860100
4023	Neoprene Chest Belt X / L	08720589860117
5.71001.2	Chest positioning Junior / Junior S	08720589860124
5.71012.0	Chest Positioning / XS	08720589860131
5.71012.1	Chest Positioning / S	08720589860148
5.71012.2	Chest Positioning / M	08720589860155
5.71012.3	Chest Positioning / L	08720589860162
5.71014.1	X Chest Positioning / S	08720589860179
5.71014.2	X Chest Positioning / M	08720589860186
5.71014.3	X Chest Positioning / L	08720589860193
5.71032.1	Chest Positioning Flex control / Non-stretch / S	08720589860209
5.71032.2	Chest Positioning Flex control / Non-stretch / M	08720589860216
5.71032.3	Chest Positioning Flex control / Non-stretch / L	08720589860223
5.71032.4	Chest Positioning Flex control / Non-stretch / XL	08720589860230
5.71034.1	X chest Positioning Flex control / Non-stretch / S	08720589860247
5.71034.2	X chest Positioning Flex control / Non-stretch / M	08720589860254
5.71034.3	X chest Positioning Flex control / Non-stretch / L	08720589860261
5.81001.1	H-Chest Positioning Flex control / Non-stretch / S	08720589860278
5.81001.2	H-Chest Positioning Flex control / Non-stretch / M	08720589860285
5.81001.3	H-Chest Positioning Flex control / Non-stretch / L	08720589860292
5.81001.4	H-Chest Positioning Flex control / Non-stretch / XL	08720589860308
5001	KB_Neoprene MP Band / S	08720589860315
5002	KB_Neoprene MP Band / M	08720589860322
5003	KB_Neoprene MP Band / L	08720589860339
6.70001.0	Hip Belt Double Adjustable / XS	08720589860346
6.70001.1	Hip Belt Double Adjustable / S	08720589860353

6.70001.2	Hip Belt Double Adjustable / M	08720589860360
6.70001.3	Hip Belt Double Adjustable / L	08720589860377
6.70001.4	Hip Belt Double Adjustable / XL	08720589860384
6.70002.0	Hip Belt Single Adjustable / XS	08720589860391
6.70002.1	Hip Belt Single Adjustable / S	08720589860407
6.70002.2	Hip Belt Single Adjustable / M	08720589860414
6.70002.3	Hip Belt Single Adjustable / L	08720589860421
6.70002.4	Hip Belt Single Adjustable / XL	08720589860438
6.70003.0	Hip Belt Centre Release Single Adjustable / XS	08720589860445
6.70003.1	Hip Belt Centre Release Single Adjustable / S	08720589860452
6.70003.2	Hip Belt Centre Release Single Adjustable / M	08720589860469
6.70003.3	Hip Belt Centre Release Single Adjustable / L	08720589860476
6.70003.4	Hip Belt Centre Release Single Adjustable / XL	08720589860483
6.70004.0	Hip Belt Centre Release Double Adjustable / XS	08720589860490
6.70004.1	Hip Belt Centre Release Double Adjustable / S	08720589860506
6.70004.2	Hip Belt Centre Release Double Adjustable / M	08720589860513
6.70004.3	Hip Belt Centre Release Double Adjustable / L	08720589860520
6.70004.4	Hip Belt Centre Release Double Adjustable / XL	08720589860537
6.70005.0	Hip Belt Pin Release Double Adjustable / XS	08720589860544
6.70005.1	Hip Belt Pin Release Double Adjustable / S	08720589860551
6.70005.2	Hip Belt Pin Release Double Adjustable / M	08720589860568
6.70005.3	Hip Belt Pin Release Double Adjustable / L	08720589860575
6.70005.4	Hip Belt Pin Release Double Adjustable / XL	08720589860582
6.70006.1	Hip Belt Aviation Release Single Adjustable / S	08720589860599
6.70006.2	Hip Belt Aviation Release Single Adjustable / M	08720589860605
6.70006.3	Hip Belt Aviation Release Single Adjustable / L	08720589860612
6.70006.4	Hip Belt Aviation Release Single Adjustable / XL	08720589860629
6.70042.0	4-point Hip Belt Single Adjustable / XS	08720589860636
6.70042.1	4-point Hip Belt Single Adjustable / S	08720589860643
6.70042.2	4-point Hip Belt Single Adjustable / M	08720589860650
6.70042.3	4-point Hip Belt Single Adjustable / L	08720589860667
6.70042.4	4-point Hip Belt Single Adjustable / XL	08720589860674
6.70043.0	4-point Hip Belt Centre Release Double Adjustable / XS	08720589860681
6.70043.1	4-point Hip Belt Centre Release Double Adjustable / S	08720589860698
6.70043.2	4-point Hip Belt Centre Release Double Adjustable / M	08720589860704
6.70043.3	4-point Hip Belt Centre Release Double Adjustable / L	08720589860711
6.70043.4	4-point Hip Belt Centre Release Double Adjustable / XL	08720589860728
6.70044.0	4-point Hip Belt Double Adjustable / XS	08720589860735
6.70044.1	4-point Hip Belt Double Adjustable / S	08720589860742
6.70044.2	4-point Hip Belt Double Adjustable / M	08720589860759

6.70044.3	4-point Hip Belt Double Adjustable / L	08720589860766
6.70044.4	4-point Hip Belt Double Adjustable / XL	08720589860773
6.70045.0	4-point Hip Belt Pin Release Double Adjustable / XS	08720589860780
6.70045.1	4-point Hip Belt Pin Release Double Adjustable / S	08720589860797
6.70045.2	4-point Hip Belt Pin Release Double Adjustable / M	08720589860803
6.70045.3	4-point Hip Belt Pin Release Double Adjustable / L	08720589860810
6.70045.4	4-point Hip Belt Pin Release Double Adjustable / XL	08720589860827
6.70047.0	4 point hip belt center release adjustable / XS	08720589860834
6.70047.1	4 point hip belt center release adjustable / S	08720589860841
6.70047.2	4 point hip belt center release adjustable / M	08720589860858
6.70047.3	4 point hip belt center release adjustable / L	08720589860865
6.70047.4	4 point hip belt center release adjustable / XL	08720589860872
6.70048.2	2 point Essential belt	08720589860889
6.70048.2+	2 point hip Essential belt +	08720589860896
6.7R001.0	KB Ratchet belt single adjustable / XS	08720589860902
6.7R001.1	KB Ratchet belt single adjustable / S	08720589860919
6.7R001.2	KB Ratchet belt single adjustable / M	08720589860926
6.7R001.3	KB Ratchet belt single adjustable / L	08720589860933
6.7R001.4	KB Ratchet belt single adjustable / XL	08720589860940
6.7R002.0	KB Ratchet belt double adjustable / XS	08720589860957
6.7R002.1	KB Ratchet belt double adjustable / S	08720589860964
6.7R002.2	KB Ratchet belt double adjustable / M	08720589860971
6.7R002.3	KB Ratchet belt double adjustable / L	08720589860988
6.7R002.4	KB Ratchet belt double adjustable / XL	08720589860995
6.7RP002.0	KB Ratchet belt double adjustable Orange / XS	08720618074003
6.7RP002.1	KB Ratchet belt double adjustable Orange / S	08720618074010
6.7RP002.2	KB Ratchet belt double adjustable Orange / M	08720618074027
6.7RP002.3	KB Ratchet belt double adjustable Orange / L	08720618074034
6.7RP002.4	KB Ratchet belt double adjustable Orange / XL	08720618074041
7.70001.1	Pelvic Positioning Non-Stretch / S	08720618074058
7.70001.2	Pelvic Positioning Non-Stretch / M	08720618074065
7.70001.3	Pelvic Positioning Non-Stretch / L	08720618074072
7.70001.4	Pelvic Positioning Non-Stretch / XL	08720618074089
7.70002.1	Pelvic Positioning Stretch / S	08720618074096
7.70002.2	Pelvic Positioning Stretch / M	08720618074102
7.70002.3	Pelvic Positioning Stretch / L	08720618074119
7.70002.4	Pelvic Positioning Stretch / XL	08720618074126
8.70001.0	Ankle Positioning Velcro Closure / XS	08720618074133
8.70001.1	Ankle Positioning Velcro Closure / S	08720618074140
8.70001.2	Ankle Positioning Velcro Closure / M	08720618074157

8.70001.3	Ankle Positioning Velcro Closure / L	08720618074164
8.70001.4	Ankle Positioning Velcro Closure / XL	08720618074171
8.70002.0	Ankle Positioning Quick Release Closure / XS	08720618074188
8.70002.1	Ankle Positioning Quick Release Closure / S	08720618074195
8.70002.2	Ankle Positioning Quick Release Closure / M	08720618074201
8.70002.3	Ankle Positioning Quick Release Closure / L	08720618074218
8.70002.4	Ankle Positioning Quick Release Closure / XL	08720618074225
9.70001.0	Abduction positioning / XS	08720618074232
9.70001.1	Abduction positioning / S	08720618074249
9.70001.2	Abduction positioning / M	08720618074256
9.70001.3	Abduction positioning / L	08720618074263
kb20mmset	20 mm spare webbing set for chest positioning belts 4 pcs	08720618074287
kb25mmset	25 mm spare webbing set for chest positioning belts 4 pcs	08720618074294
KBFIXLOCK25	Kinetic Balance Fixlock 25mm	08720618074300
KBFIXLOCK40	Kinetic Balance Fixlock 40mm	08720618074317
Z5.71022.1	Chest Positioning zipper / S	08720618074324
Z5.71022.2	Chest Positioning zipper / M	08720618074331
Z5.71022.3	Chest Positioning zippers / L	08720618074348
KB Chest TDC	TenderCare Chest Positioning	08720618074270