



**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: Scheepmakerstraat 27
2222AB Katwijk aan Zee
The Netherlands

SRN (single registration number): NL-IM-000003917

Basic UDI-DI: 872058986008720UZ

Name of the devices: Chest-, Hip-, Pelvis-, Ankle- and Assorted 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 multi-use, non-sterile products.

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: Katwijk aan Zee, January 1st 2024

Issued by: Mari Genova
Business Unit Manager

Signature:

A handwritten signature in black ink, appearing to read 'Mari Genova'.

Appendix 1 Product List

Artikel Code	Omschrijving	GTIN
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 Stretch / XS	08720589860131
5.71012.1	Chest Positioning Stretch / S	08720589860148
5.71012.2	Chest Positioning Stretch / M	08720589860155
5.71012.3	Chest Positioning Stretch / L	08720589860162
5.71014.1	X-Chest Positioning Stretch / S	08720589860179
5.71014.2	X-Chest Positioning Stretch / M	08720589860186
5.71014.3	X-Chest Positioning Stretch / 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	Neoprene Multi-Purpose Band / S	08720589860315
5002	Neoprene Multi-Purpose Band / M	08720589860322
5003	Neoprene Multi-Purpose Band / L	08720589860339
6.70001.0	2-point Hip Belt Side Release / Double Adjustable / XS	08720589860346
6.70001.1	2-point Hip Belt Side Release / Double Adjustable / S	08720589860353
6.70001.2	2-point Hip Belt Side Release / Double Adjustable / M	08720589860360
6.70001.3	2-point Hip Belt Side Release / Double Adjustable / L	08720589860377
6.70001.4	2-point Hip Belt Side Release / Double Adjustable / XL	08720589860384
6.70002.00	2-point Hip Belt Side Release / Single Adjustable / XXS	08720589860186
6.70002.0	2-point Hip Belt Side Release / Single Adjustable / XS	08720589860391

Declaration of Conformity

6.70002.1	2-point Hip Belt Side Release / Single Adjustable / S	08720589860407
6.70002.2	2-point Hip Belt Side Release / Single Adjustable / M	08720589860414
6.70002.3	2-point Hip Belt Side Release / Single Adjustable / L	08720589860421
6.70002.4	2-point Hip Belt Side Release / Single Adjustable / XL	08720589860438
6.70003.0	2-point Hip Belt Centre Release / Single Adjustable / XS	08720589860445
6.70003.1	2-point Hip Belt Centre Release / Single Adjustable / S	08720589860452
6.70003.2	2-point Hip Belt Centre Release / Single Adjustable / M	08720589860469
6.70003.3	2-point Hip Belt Centre Release / Single Adjustable / L	08720589860476
6.70003.4	2-point Hip Belt Centre Release / Single Adjustable / XL	08720589860483
6.70004.0	2-point Hip Belt Centre Release / Double Adjustable / XS	08720589860490
6.70004.1	2-point Hip Belt Centre Release / Double Adjustable / S	08720589860506
6.70004.2	2-point Hip Belt Centre Release / Double Adjustable / M	08720589860513
6.70004.3	2-point Hip Belt Centre Release / Double Adjustable / L	08720589860520
6.70004.4	2-point Hip Belt Centre Release / Double Adjustable / XL	08720589860537
6.70005.0	2-point Hip Belt Pin Release / Double Adjustable / XS	08720589860544
6.70005.1	2-point Hip Belt Pin Release / Double Adjustable / S	08720589860551
6.70005.2	2-point Hip Belt Pin Release / Double Adjustable / M	08720589860568
6.70005.3	2-point Hip Belt Pin Release / Double Adjustable / L	08720589860575
6.70005.4	2-point Hip Belt Pin Release / Double Adjustable / XL	08720589860582
6.70006.1	2-point Hip Belt Aviation Release / Single Adjustable / S	08720589860599
6.70006.2	2-point Hip Belt Aviation Release / Single Adjustable / M	08720589860605
6.70006.3	2-point Hip Belt Aviation Release / Single Adjustable / L	08720589860612
6.70006.4	2-point Hip Belt Aviation Release / Single Adjustable / XL	08720589860629
6.70042.0	4-point Hip Belt Side Release / Single Adjustable / XS	08720589860636
6.70042.1	4-point Hip Belt Side Release / Single Adjustable / S	08720589860643
6.70042.2	4-point Hip Belt Side Release / Single Adjustable / M	08720589860650
6.70042.3	4-point Hip Belt Side Release / Single Adjustable / L	08720589860667
6.70042.4	4-point Hip Belt Side Release / 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 Side Release / Double Adjustable / XS	08720589860735
6.70044.1	4-point Hip Belt Side Release / Double Adjustable / S	08720589860742
6.70044.2	4-point Hip Belt Side Release / Double Adjustable / M	08720589860759
6.70044.3	4-point Hip Belt Side Release / Double Adjustable / L	08720589860766
6.70044.4	4-point Hip Belt Side Release / 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

Declaration of Conformity

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 / Single Adjustable / XS	08720589860834
6.70047.1	4-point Hip Belt Center Release / Single Adjustable / S	08720589860841
6.70047.2	4-point Hip Belt Center Release / Single Adjustable / M	08720589860858
6.70047.3	4-point Hip Belt Center Release / Single Adjustable / L	08720589860865
6.70047.4	4-point Hip Belt Center Release / Single Adjustable / XL	08720589860872
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 / Hook and Loop Closure / XS	08720618074133
8.70001.1	Ankle Positioning / Hook and Loop Closure / S	08720618074140
8.70001.2	Ankle Positioning / Hook and Loop Closure / M	08720618074157
8.70001.3	Ankle Positioning / Hook and Loop Closure / L	08720618074164
8.70001.4	Ankle Positioning / Hook and Loop Closure / XL	08720618074171
8.70002.0	Ankle Positioning / Side Release Closure / XS	08720618074188
8.70002.1	Ankle Positioning / Side Release Closure / S	08720618074195
8.70002.2	Ankle Positioning / Side Release Closure / M	08720618074201
8.70002.3	Ankle Positioning / Side Release Closure / L	08720618074218
8.70002.4	Ankle Positioning / Side 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
Z5.71022.1	Chest Positioning Zipper Stretch / S	08720618074324
Z5.71022.2	Chest Positioning Zipper Stretch / M	08720618074331
Z5.71022.3	Chest Positioning Zippers Stretch / L	08720618074348
KB Chest TDC	TenderCare Chest Positioning	08720618074270
1.7001.0	Contrabelts 25mm siderelease	08720589860001
1.7002.0	Contrabelts 40mm siderelease	08720589860018
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
KBFXLOCK25	Kinetic Balance Fixlock 25mm	08720618074300
KBFXLOCK40	Kinetic Balance Fixlock 40mm	08720618074317

Declaration of Conformity