



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 Netherland
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, June 12th 2023

Issued by: Gerhard van Geest
Partner

Signature:

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
6.70002.0	2-point Hip Belt Side Release / Single Adjustable / XS	08720589860391

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

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
6.70048.2	2-point Essential belt	08720589860889
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

KBFIXLOCK40

Kinetic Balance Fixlock 40mm

08720618074317