

DECLARATION OF CONFORMITY

Regulation on Medical Devices (EU) 2017/745

This EU Declaration of Conformity is issued under the sole responsibility of Ortho Medic Care NV

1) Manufacturer

Ortho Medic Care Nv

Evolis 100

8500 Kortrijk

Belgium

SRN: BE-MF-000019601

BASIC UDI-DI 5430000726009

2) Product(s)

- **DETECTAPLAST® and PROTECTAPLAST® ADHESIVE PLASTERS**

see appendix

3) The product(s) described above is/ are in conformity with:

<u>Title</u>	
Medical Device Regulation	2017/745

4) Additional information

Conformity assessment procedure for CE marking: Medical Device Regulation, Annex V

Registration nr.: BE/CA01/1-12881-MMD-00001

Product standards:

ISO 10993-1

ISO 10993-5

ISO 10993-7

ISO 10993-10

ISO 10993-12

ISO 14644-3,4

Intended purpose; For covering skin scratches and minor wounds.

Kortrijk, 2022/10/25

Wouter Jacobs, Director



Appendix

Date: 2022-04-02

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
DETECTAPLAST ELASTIC ROLL 6CMX5M IN DISPENSER	5600E	Class I/ rule 4	5407006141563
PROTECTAPLAST ELASTIC ROLL 6CMX5M IN DISPENSER	5600EP	Class I/ rule 4	5407006141440
DETECTAPLAST SECOND SKIN 51X72MM - 50PCS	7951	Class I/ rule 4	5407006140931
DETECTAPLAST SECOND SKIN 5X7CM - 20PCS	7951PH_FRNL	Class I/ rule 4	5430000726054
DETECTAPLAST SECOND SKIN 5X7CM - 20PCS	7951PH_ENDE	Class I/ rule 4	5407006140924
DETECTAPLAST PREMIUM 25X72MM - 100PCS	8025	Class I/ rule 4	5407006140566
DETECTAPLAST PREMIUM BUTTERFLY 68X38MM - 50PCS	8045	Class I/ rule 4	5407006140580
DETECTAPLAST PREMIUM ANCHOR 68X38MM - 50PCS	8046	Class I/ rule 4	5407006140597
DETECTAPLAST PREMIUM 120X20MM - 100PCS	8047	Class I/ rule 4	5407006140603
DETECTAPLAST PREMIUM 180X20MM	8048	Class I/ rule 4	5407006140610
DETECTAPLAST DISPENSER PREMIUM 180X20MM - 50PCS	80485	Class I/ rule 4	5407006141013
DETECTAPLAST PREMIUM 50X72MM - 50PCS	8051	Class I/ rule 4	5407006140573
DETECTAPLAST UNIVERSAL 6CMX5M- 1PC	8055	Class I/ rule 4	5407006140542
DETECTAPLAST UNIVERSAL 8CMX5M - 1PC	8056	Class I/ rule 4	5407006140559
DETECTAPLAST BLUE TAPE 2,5CMX5M	8057	Class I/ rule 4	5407006142096
PROTECTAPLAST SOFT 19*72mm	8060P	Class I/ rule 4	5407006141365
PROTECTAPLAST SOFT 25*72mm	8061P	Class I/ rule 4	5407006141372
PROTECTAPLAST SOFT 25X25MM - 100 PCS	8062P	Class I/ rule 4	5407006141396
PROTECTAPLAST SOFT 50x72mm - 50 pcs	8064P	Class I/ rule 4	5407006141389
PROTECTAPLAST SOFT 6CMX5M	8065P	Class I/ rule 4	5407006141426

	Declaration of Conformity	STED130-2022 vs. 1.0
		Page: 3 of 6

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
PROTECTAPLAST SOFT ASSORTED	8067P	Class I/ rule 4	5407006141402
PROTECTAPLAST SOFT 6CMX1M	8068P	Class I/ rule 4	5407006141419
PROTECTAPLAST SOFT 6CMX1M	8068PH	Class I/ rule 4	5407006141587
PROTECTAPLAST NOSE PLASTER - 30PCS	8070P	Class I/ rule 4	5430000726351
PROTECTAPLAST HEEL PLASTER - 5PCS	8071P.5	Class I/ rule 4	5430000726832
PROTECTAPLAST INVISIBLE PLASTER – 12 PCS	010100P	Class I/ rule 4	5430000726894
PROTECTAPLAST KIDS PLASTERS - 100 PCS	8082P	Class I/ rule 4	5430000726924
PROTECTAPLAST KIDS PLASTERS – 20 PCS	8082PH	Class I/ rule 4	5407006140399
PROTECTAPLAST PRO ELASTIC 6CMX1M - 1PCS	8112P	Class I/ rule 4	5407006141242
PROTECTAPLAST PRO ELASTIC 6CMX1M - 1PCS	8112PH	Class I/ rule 4	2016058112006
PROTECTAPLAST PRO ELASTIC SKIN 4CMX5M	8114P	Class I/ rule 4	5407006141259
PROTECTAPLAST PRO ELASTIC 6CMX5M	8115P	Class I/ rule 4	5407006141266
PROTECTAPLAST ELASTIC 8CMX5M	8116P	Class I/ rule 4	5407006141273
PROTECTAPLAST PRO ELASTIC 19X72MM	8120P	Class I/ rule 4	5407006141136
PROTECTAPLAST PRO ELASTIC 25X72MM	8121P	Class I/ rule 4	5407006141143
PROTECTAPLAST ELASTIC ASSORTED - 100 pcs	8122EP	Class I/ rule 4	5407006141174
PROTECTAPLAST PRO WASHPROOF MIX - 100 PCS	8122UP	Class I/ rule 4	5407006141334
PROTECTAPLAST PRO WASHPROOF MIX - 100 PCS	8122UPH	Class I/ rule 4	5407006141594
PROTECTAPLAST ELASTIC BUTTERFLY	8125P	Class I/ rule 4	5407006141150
PROTECTAPLAST ELASTIC KNUCKLE	8126P	Class I/ rule 4	5407006141167
PROTECTAPLAST ELASTIC 12X2 CM - 50PCS	81279P	Class I/ rule 4	5407006141228
PROTECTAPLAST PRO ELASTIC 12x2 CM - 100PCS	8127P	Class I/ rule 4	5407006141181
PROTECTAPLAST PRO ELASTIC 12x2 CM - 50PCS	81275P	Class I/ rule 4	5407006141457
PROTECTAPLAST PRO ELASTIC 18X2 CM - 50PCS	81289P	Class I/ rule 4	5407006141235
PROTECTAPLAST ELASTIC 18X2CM - 100PCS	8128P	Class I/ rule 4	5407006141204
PROTECTAPLAST ELASTIC 18X2CM - 50PCS	81285P	Class I/ rule 4	5407006141464
PROTECTAPLAST PRO ELASTIC 12X3CM - 100PCS	8137P	Class I/ rule 4	5407006141198

	Declaration of Conformity	STED130- 2022 vs. 1.0
		Page: 4 of 6

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
PROTECTAPLAST ELASTIC 180x30 MM - 100STUKS	8138P	Class I/ rule 4	5407006141211
DETECTAPLAST UNIVERSAL 19X72MM	8140	Class I/ rule 4	5407006140467
DETECTAPLAST UNIVERSAL 25X72MM - 100PCS	8141	Class I/ rule 4	5407006140474
DETECTAPLAST UNIVERSAL 38X38 MM - 100PCS	8142	Class I/ rule 4	5430000726412
DETECTAPLAST ELASTIC ELASTIC MIX – 100 PCS	8142E	Class I/ rule 4	5407006140689
DETECTAPLAST UNIVERSAL ASSORTED - 100PCS	8142U	Class I/ rule 4	5407006140528
DETECTAPLAST ELASTIC ASSORTED - 40PCS	8142EPH_ENDE	Class I/ rule 4	5407006140122
DETECTAPLAST ELASTIC ASSORTED FRNL - 40PCS	8142EPH_FRNL	Class I/ rule 4	5430000726023
DETECTAPLAST WATERPROOF ASSORTED - 40PCS	8142UPH_ENDE	Class I/ rule 4	5407006140139
DETECTAPLAST WATERPROOF ASSORTED - 40PCS	8142UPH_FRNL	Class I/ rule 4	5430000726077
DETECTAPLAST UNIVERSAL 38X72MM - 50PCS	8143	Class I/ rule 4	5407006140481
DETECTAPLAST UNIVERSAL 50X72MM-50PCS	8144	Class I/ rule 4	5407006140498
DETECTAPLAST UNIVERSAL 120X20MM - 100PCS	8147	Class I/ rule 4	5407006140504
DETECTAPLAST UNIVERSAL 180X20MM - 100PCS	8148	Class I/ rule 4	5407006140511
DETECTAPLAST DISPENSER UNIVERSAL 180X20MM - 50PCS	81485	Class I/ rule 4	5407006141006
PROTECTAPLAST PRO WP 9X38MM - 100 PCS	8155P	Class I/ rule 4	5407006141983
PROTECTAPLAST PRO WP 19X38MM - 100 PCS	8156P	Class I/ rule 4	5407006141853
PROTECTAPLAST PRO WP 38X38MM - 100 PCS	8157P	Class I/ rule 4	5407006141990
PROTECTAPLAST PRO WP 38X72MM - 100 PCS	8158P	Class I/ rule 4	5407006142003
PROTECTAPLAST PRO WASHPROOF 19*72 MM - 100 PCS	8170P	Class I/ rule 4	5407006141280
PROTECTAPLAST PRO WASHPROOF 25X72 MM - 100 PCS	8171P	Class I/ rule 4	5407006141297
PROTECTAPLAST PRO WASHPROOF SPOT 25MM - 100 PCS	8172P	Class I/ rule 4	5407006141303
PROTECTAPLAST PRO WP BUTTERFLY	8175P	Class I/ rule 4	5407006141310
PROTECTAPLAST PRO WP KNUCKLE	8176P	Class I/ rule 4	5407006141327
PROTECTAPLAST PRO WP 12X2CM - 100 PCS	8177P	Class I/ rule 4	5407006141341

	Declaration of Conformity	STED130- 2022 vs. 1.0
		Page: 5 of 6

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
PROTECTAPLAST PRO WP 12X2CM - 50 PCS	81775P	Class I/ rule 4	5407006141471
PROTECTAPLAST PRO WP 18X2CM - 100 PCS	8178P	Class I/ rule 4	5407006141358
PROTECTAPLAST PRO WP 18X2CM - 50 PCS	81785P	Class I/ rule 4	5407006141488
DETECTAPLAST ELASTIC 1M X 6CM	8188	Class I/ rule 4	5407006140948
PROTECTAPLAST PRO WASHPROOF 19*72 MM - PINK	8179	Class I/ rule 4	5407006143086
DETECTAPLAST ELASTIC 6CMX1M - 1PCS	8188PH_ENDE	Class I/ rule 4	5407006140115
DETECTAPLAST ELASTIC 6CMX1M - 1PCS	8188PH_FRNL	Class I/ rule 4	5430000726047
PROTECTAPLAST PU CLEAR 25*72MM	8191P	Class I/ rule 4	5430000726856
PU CLEAR PLASTER 51*72MM - 50PCS	8195P	Class I/ rule 4	5430000726870
DETECTAPLAST PIERCING 9X38MM - 50PCS	8238	Class I/ rule 4	5407006140672
DETECTAPLAST ELASTIC 19X72MM - 100PCS	8240	Class I/ rule 4	5407006140627
DETECTAPLAST ELASTIC 25X72MM - 100PCS	8241	Class I/ rule 4	5407006140634
DETECTAPLAST ELASTIC BUTTERFLY - 50PCS	8245	Class I/ rule 4	5407006140658
DETECTAPLAST ELASTIC ANCHOR - 50PCS	8246	Class I/ rule 4	5407006140665
DETECTAPLAST ELASTIC 50X72MM - 50PCS	8251	Class I/ rule 4	5407006140641
DETECTAPLAST ELASTIC 6CMX5M	8255	Class I/ rule 4	5407006140771
DETECTAPLAST ELASTIC 8CMX5M	8256	Class I/ rule 4	5407006140788
DETECTAPLAST ELASTIC 6CM X 25M	8257	Class I/ rule 4	5407006140795
DETECTAPLAST ELASTIC 8CMX25M	8258	Class I/ rule 4	5407006140801
DETECTAPLAST ELASTIC 120X20MM - 100PCS	8347	Class I/ rule 4	5407006140719
DETECTAPLAST DISPENSER ELASTIC 120X20MM - 50PCS	83475	Class I/ rule 4	5407006141020
DETECTAPLAST ELASTIC 180X20MM - 100PCS	8348	Class I/ rule 4	5407006140726
DETECTAPLAST DISPENSER ELASTIC 180X20MM - 50PCS	83485	Class I/ rule 4	5407006141037
DETECTAPLAST ELASTIC 180X20MM - 50 PCS	83489	Class I/ rule 4	5407006140733
DETECTAPLAST ELASTIC 18X2CM - 32PCS	83489PH_ENDE	Class I/ rule 4	5407006140108
DETECTAPLAST ELASTIC 18X2CM - 32PCS	83489PH_FRNL	Class I/ rule 4	5430000726030

	Declaration of Conformity	STED130- 2022 vs. 1.0
		Page: 6 of 6

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
DETECTAPLAST ELASTIC 120X30MM - 100PCS	8447	Class I/ rule 4	5407006140757
DETECTAPLAST DISPENSER ELASTIC 120X30MM - 50 PC	84475	Class I/ rule 4	5407006141044
DETECTAPLAST ELASTIC 180X30MM	8448	Class I/ rule 4	5407006140764
DETECTAPLAST DISPENSER ELASTIC 180X30MM - 50 PCS	84485	Class I/ rule 4	5407006141051
DETECTAPLAST ELASTIC MIX DIN 13157 – 28 PCS	8503.0	Class I/ rule 4	5407006140016
DETECTAPLAST ELASTIC MIX DIN 13169 – 56 PCS	8504.0	Class I/ rule 4	5407006140023
DETECTAPLAST ELASTIC X-RAY 25X72MM - 100PCS	8540	Class I/ rule 4	5407006140986
DETECTAPLAST ELASTIC X-RAY 180X20MM - 100PCS	8548	Class I/ rule 4	5407006140993
DETECTAPLAST PREMIUM METAL & X RAY 25X72MM - 100PCS	8550	Class I/ rule 4	5430000727013
DETECTAPLAST PREMIUM METAL & X RAY 50X72MM - 50PCS	8555	Class I/ rule 4	5430000727020
DETECTAPLAST PREMIUM METAL & X RAY MIX - 100PCS	8552	Class I/ rule 4	5407006142072
DETECTAPLAST PREMIUM METAL & X RAY BUTTERFLY - 50PCS	8554	Class I/ rule 4	5407006142058
DETECTAPLAST PREMIUM METAL & X RAY KNUCKLE - 50PCS	8556	Class I/ rule 4	5407006142065
DETECTAPLAST PREMIUM METAL & X RAY 180X20MM - 100PCS	8558	Class I/ rule 4	5430000727037
DETECTAPLAST METAL & X RAY 18X2CM - 50PCS	85589	Class I/ rule 4	5407006140979
PROTECTAPLAST Blister plaster assorted - 6PCS	8810	Class I/ rule 4	5407006140917
DETECTAPLAST HYDROGEL 110X67MM - 10PCS	9300	Class I/ rule 4	5407006140955
Tear & Wear Detectaplast Waterproof 25*72mm – 40 pcs	8141PD	Class I/ rule 4	5407006141914
Tear & Wear Detectaplast Elastic 25*72mm – 36 pcs	8241PD	Class I/ rule 4	5407006141907
Tear & Wear Protectaplast Universal 25*72mm – 40 pcs	8171PD	Class I/ rule 4	5407006141891
Tear & Wear Protectaplast Elastic 25*72mm – 36 pcs	8121PD	Class I/ rule 4	5407006141884