

DECLARATION OF CONFORMITY

1) Manufacturer

Ortho Medic Care Nv
 Evolis 100
 8500 Kortrijk
 Belgium

2) Product(s)

- DETECTAPLAST® and PROTECTAPLAST® bandages, dressings and tapes
see appendix

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

<u>Title</u>	<u>Document No.</u>
Medical Device Directive	93/42/EEC

4) Additional information

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII

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

Kortrijk, 2020/03/19

Wouter Jacobs, Director



Appendix

Date: 2020-03-19

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE- compliance
FOAM BANDAGE SOFT BLUE 6CMX4,5M	5500	Class I/ rule 4	
FOAM BANDAGE SOFT BLUE 3CM X 4,5M	5501	Class I/ rule 4	
FOAM BANDAGE SOFT BLUE 6CM X 1M	5502	Class I/ rule 4	
FOAM BANDAGE SOFT SKIN 6CMX4,5M	5510	Class I/ rule 4	
FOAM BANDAGE SOFT SKIN 3CM X 4,5M	5511	Class I/ rule 4	
FOAM BANDAGE SOFT SKIN 6CM X 1M	5512	Class I/ rule 4	
DETECTAPLAST TRIANGULAR BANDAGE BLUE	7061	Class I/ rule 4	
DETECTAPLAST BLUE TAPE 2,5CMX5M	8057	Class I/ rule 4	
DETECTAPLAST FIRST AID DRESSING 6CMX4M (PAD OF 6CMX8CM)	9062	Class I/ rule 4	
DETECTAPLAST ELASTIC BANDAGES – ASSORTMENT 12PCS	90625	Class I/ rule 4	
DETECTAPLAST ELASTIC BANDAGE 6CMX4M - 1PC	9064	Class I/ rule 4	
DETECTAPLAST FIRST AID DRESSING 8CMX4M - 1 PC	9082	Class I/ rule 4	
DETECTAPLAST ELASTIC BANDAGE 8CMX4M	9084	Class I/ rule 4	
SELF ADHERENT BANDAGE 5CM X4.5M - 1PC	9085	Class I/ rule 4	
DETECTAPLAST COHESIVE BANDAGES - ASSORT. 7PCS	90855	Class I/ rule 4	
SELF ADHERENT BANDAGE 2,5CM X 4.5M - 1PC	9086	Class I/ rule 4	
SELF ADHERENT BANDAGE 7CM X 4.5M - 1PC	9087	Class I/ rule 4	

¹ See risk classification in Medical Device Directive, annex IX