

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® bandages <i>see appendix</i>
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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

Kortrijk, 2021/06/02

Wouter Jacobs, Director



Appendix

Date: 2021-06-02

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
DETECTAPLAST FIRST AID DRESSING 6CMX4M (PAD OF 6CMX8CM)	9062	Class I/ rule 4	5407006141631
DETECTAPLAST ELASTIC BANDAGES – ASSORTMENT 12PCS	90625	Class I/ rule 4	5430000726498
DETECTAPLAST ELASTIC BANDAGE 6CMX4M - 1PC	9064	Class I/ rule 4	5407006141617
DETECTAPLAST FIRST AID DRESSING 8CMX4M - 1 PC	9082	Class I/ rule 4	5407006141648
DETECTAPLAST ELASTIC BANDAGE 8CMX4M	9084	Class I/ rule 4	5407006141624
SELF ADHERENT BANDAGE 5CM X4.5M - 1PC	9085	Class I/ rule 4	5407006141662
DETECTAPLAST COHESIVE BANDAGES - ASSORT. 7PCS	90855	Class I/ rule 4	5430000726504
SELF ADHERENT BANDAGE 2,5CM X 4.5M - 1PC	9086	Class I/ rule 4	5407006141655
SELF ADHERENT BANDAGE 2,5CM X 4.5M - 3PCS	90863	Class I/ rule 4	5430000726092
SELF ADHERENT BANDAGE 7CM X 4.5M - 1PC	9087	Class I/ rule 4	5407006141679