

## 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: Not assigned yet

**2) Product(s)**

- DETECTAPLAST® and PROTECTAPLAST® tapes  
*see appendix*

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

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

**4) Additional information**

Conformity assessment procedure for CE marking: Medical Device Regulation,  
 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 <sup>1</sup>	UDI-DI
DETECTAPLAST BLUE TAPE 2,5CMX5M	8057	Class I/ rule 4	5407006141693
NON WOVEN TAPE 1.25 CM X 5M	8160P	Class I/ rule 4	5407006141747
NON WOVEN TAPE 2.50 CM X 5M	8161P	Class I/ rule 4	5407006141754
ELASTIC FABRIC TAPE 1.25CM X 5M	8164	Class I/ rule 4	5407006141761
ELASTIC FABRIC TAPE 2.50CM X 5M	8165	Class I/ rule 4	5407006141778

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