

## 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)**

<ul style="list-style-type: none"> <li>- DETECTAPLAST® foam bandages</li> <li>- PROTECTAPLAST® foam bandages</li> </ul> <p><i>see appendix</i></p>
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**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, 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 <sup>1</sup>	UDI-DI
DETECTAPLAST FOAM BANDAGE 6CMX4.5M	5500	Class I/ rule 4	5430000726320
DETECTAPLAST FOAM BANDAGE 3CMX4.5M	5501	Class I/ rule 4	5430000726603
DETECTAPLAST FOAM BANDAGE 6CMX1M	5502	Class I/ rule 4	5430000726610
PROTECTAPLAST FOAM BANDAGE 6CMX4.5M	5510	Class I/ rule 4	5430000726337
PROTECTAPLAST FOAM BANDAGE 3CMX4.5M	5511	Class I/ rule 4	5430000726962
PROTECTALAST FOAM BANDAGE 6CMX1M	5512	Class I/ rule 4	5407006140047