

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® Burn**
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,

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, 2023/02/01

Wouter Jacobs, Director



Appendix

Date: 2023-02-01

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	UDI-DI
Burn Gel Dressing 10 x 10	9302	Class II	5407006144052
