FIOMEX Sp. z o.o.
41-303 Dąbrowa Górnicza, ul. Podlesie 3
NIP 6252454318 Regon 361953743
(1)

CE

Dąbrowa Górnicza, 01.09.2023r

Declaration of Conformity

We, Fiomex Sp. z o.o. 41-303 Dąbrowa Górnicza, Podlesie 3, Poland, hereby declare under our sole responsibility that the CE marked products of which this declaration relates:

Basic UDI-DI: 5903714204SterilReelsT8

Sterilization Reel „begreat"

- width 55mm, length 200m
- width 75mm, length 200m
- width 100mm, length 200m
- width 150mm, length 200m
- width 200mm, length 200m

product purpose:
paper and foil reels for sterilization of medical instruments,

was classified as **class I**; **rule 1** in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42EEC.

List of harmonized standards in accordance with the EU directive:

- **EN ISO 15223-1:2012**
- **EN 980:2008**
- **EN 1041:2009**
- **EN 14971:2012**
- **EN 62366:2008**
- **EN ISO 11607:2009**
- **EN 868-3:2009**

The conformity assessment procedure was carried out in accordance with Annex II and III of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

The manufacturer declares that the product complies with Regulation 2017/745.

Digitally signed by Benderschi Ruslan
Date: 2024.01.19 15:15:06 EET
Reason: MoldSign Signature
Location: Moldova

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