



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: 5903714204SterilPouches4X

Sterilization Pouches „begreat”

- /bsp1/ - 57x100mm
- /bsp2/ - 70x225mm
- /bsp3/ - 90x135mm
- /bsp4/ - 90x230mm
- /bsp5/ - 135x255mm

product purpose:

self-sealing paper and foil bag for sterilization of medical instruments,ts,

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 93/42/EEC.

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.

FIOMEX Sp. z o.o.
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