

**EU DECLARATION OF CONFORMITY**

Manufacturer: **MERCATOR MEDICAL S.A.**  
UL. H.MODRZEJEWSKIEJ 30  
31-327 KRAKÓW, POLSKA

Declares under its sole responsibility that non-sterile examination and protective gloves:

| Brand                                      | Type                               | Sizes                | Batch numbers       |
|--|------------------------------------|----------------------|---------------------|
| <b>vinylex® blue</b>                       | vinyl, powder-free, for single use | XS (5-6) - XL (9-10) | a'100 RD20216001-05 |
| <b>Basic UDI-DI: 5906615 RD NS V PF AL</b> |                                    |                      |                     |

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

The products described above are also classified as Personal Protective Equipment Category I and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: EN 420:2003 + A1:2009.

Date and place of issue:  
05.05.2020, Kraków

Signed on the behalf of the Manufacturer:



Wojciech Hercka  
Product Documentation Manager

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XI Wydział Gospodarczy KRS, KRS: 0000036244  
Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN  
NIP: 677-10-36-424, REGON: 350967107  
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