

# DECLARATION OF CONFORMITY

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 Trade Register: Amtsgericht Mönchengladbach HRB19993

**We declare under our sole responsibility that the product:**

|                       |   |
|-----------------------|---|
| <i>Equipment name</i> | Infection control gown  |
| <i>Model</i>          | S 500 blau  |
| <i>Type</i>           | GEOBN ( <i>gown – elastic bond – overlock seam – blue – non-sterile</i> ) |
| <i>Sizes</i>          | S, M, L, XL   |



Infection control gown



elastic bond



overlock seam

**to which this declaration relates is in conformity with the following standards:**

|     |                                 |  |   |
|-----|---------------------------------|--|---|
| EU  | <i>Protection certification</i> | CE 0121<br>(EU) 2016/425 PPE Cat III<br>DIN EN 14126:2004, Correction 2005<br>DIN EN 13034:2005 + A1:2009<br>DIN EN ISO 13688:2019 | Certified<br>The module C2 is supervised by IFA |
|     | <i>Medical certification</i>    | DIN EN 13795-1 <b>high performance</b><br>DIN EN ISO 10993-5, 10993-10<br>(EU) 2017/745 MDR Class I                                |   |
|     |                                 |  | Certification in preparation                    |
| USA | <i>Medical certification</i>    | ASTM F1670 • ASTM 1671   | Certified                                       |
|     | <i>Protection certification</i> | ANSI/AAMI P70:2012 <b>level IV</b>   | Certified                                       |

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