

## EU Declaration of Conformity

for a medical device class I (according to the EU regulation 2017/745, annex IV)

The manufacturer:

**Franz Mensch GmbH**  
**Werner-von-Siemens-Str. 2**  
**D - 86807 Buchloe**

declares under sole responsibility, that the class I medical device according to the classification rules of the EU regulation 2017/745, annex VIII

|                    |  |
|--------------------|--|
| <b>Item REF</b>    | <b>27060B</b>                                    |
| <b>Description</b> | <b>Nitrile gloves Safe Premium   powder-free</b> |
| <b>Brand</b>       | <b>Hygostar</b>                                  |
| <b>Version</b>     | <b>Packing unit: Carton</b>                      |
|                    | <b>Color: White</b>                              |
|                    | <b>Size: 7/S</b>                                 |
|                    | <b>Length: 24cm</b>                              |
|                    | <b>PU: bag</b>                                   |

complies and meets all the provisions of the conformity assessment procedure of the EU regulation 2017/745 (annex I).

in accordance with confirmed records, test results or certificates, complies/comply with the requirements of the relevant harmonization legislation:

**EN 455-1:2020**  
**EN 455-2:2015+A1:2011**  
**EN 455-3:2015**  
**EN 455-4:2009**

The achieved performance levels of this medical device correspond to:

Signed for and on behalf of Franz Mensch GmbH,

Buchloe, 31.05.2021

  
Amanda Kreuzmann  
Head of Quality Management