

## EU Declaration of Conformity

### For a single use medical device class I

The manufacturer:

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

**SRN:** **DE-MF-000021137**

declares under its sole responsibility that the medical device of class I according to Annex VIII of the Regulation (EU) 2017/745

|                    |  |
|--------------------|--|
| <b>Item REF</b>    | <b>261102</b>                                |
| <b>Description</b> | <b>Nitrile gloves Safe Fit   powder-free</b> |
| <b>Brand</b>       | <b>Hygonorm</b>                              |
| <b>Version</b>     | <b>Colour: white</b>                         |
|                    | <b>Size: 9/L</b>                             |
|                    | <b>Length: 24cm</b>                          |
|                    | <b>PU: dispenser box (100 pcs.)</b>          |

**Basic – UDI** **40155440110GP**

**Intended use** **For third-party protection (protection against germ transmission) in the hospital and care sector**

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

complies with all requirements of regulation EU 2017/745 and its annexes in accordance with the conformity assessment procedure set out in annexes II and III of regulation EU 2017/745.

Furthermore, the manufacture and release of the devices are carried out in accordance with the specifications defined in the associated technical documentation, applied standards and normative documents. The medical device bears the CE conformity marking.

This declaration of conformity is valid until a new declaration of conformity is issued due to the modification of the medical device.

Signed for and on behalf of Franz Mensch GmbH,

Buchloe, 08.06.2022



Achim Theiler  
Management