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

Item REF	**2606**
Description	**Nitrile gloves Control | powdered**
Brand	**Hygostar**
Version	**Packing unit: Carton** **Color: Blue** **Size: 7/S** **Length: 24cm**

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:

AQL 1,5

Signed for and on behalf of Franz Mensch GmbH,

Buchloe, 31.05.2021

Amanda Kreuzmann
Head of Quality Management

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