

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

Item REF	261002
Description	Nitrile gloves Safe Fit powder-free
Brand	Hygonorm
Version	Colour: white
	Size: 10/XL
	Length: 24cm
	PU: dispenser box (100 pcs.)

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