

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	B277780
Description	Gown PP, PE full laminated
Brand	Hygostar
Material	PP
Version	Colour: blue
	Length: 120cm
	Circumference: 140cm
	Size: 10/XL

Basic – UDI 40155440235HC

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

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.

Das Material erfüllt zusätzlich die Anforderungen der folgenden Norm: EN 14126:2003

Dabei wurden folgende Leistungsstufen erreicht:

EN ISO 16603/ EN ISO 16604: Klasse 6

EN ISO 22610: Klasse 6

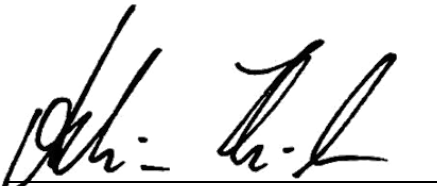
EN ISO 22611: Klasse 3

EN ISO 22612: Klasse 3

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, 31.07.2023



Achim Theiler
Management