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	**277100**
Description	**Gowns Eco with knitted cuffs | PP**
Brand	**Hygonorm**
Version	**Colour: white** **Size: L** **Length: 115cm** **Circumference: 140cm**
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.

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, 14.03.2022

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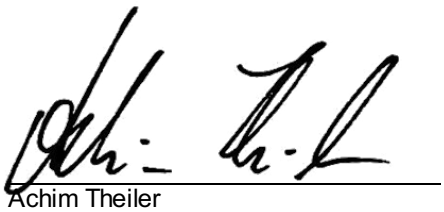
Franz Mensch is a
ISO certified company
DIN EN ISO 9001:2015



Achim Theiler
Person responsible for regulatory compliance
PRRC - Art. 15 MDR

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