

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 277188

Description Gowns Eco with knitted cuffs | PP

Brand Hygonorm Version Colour: yellow 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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Achim Theiler

Person responsible for regulatory

compliance

PRRC - Art. 15 MDR