

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

Nursing shirts | SMS

declares under its sole responsibility that the medical device of class I according to Annex VIII of the Regulation (EU) 2017/745

27556

Hygostar SMS

Colour: blue Size: XXL Lenath: 80cm

Item REF
Description
Brand
Material
Version

Basic – UDI

Intended use

40155440234HA

Circumference: 134cm

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,

Updated 07.08.2023

Franz Mensch GmbH Werner-von-Siemens-Str. 2 86807 Buchloe, Germany

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Contact us at:

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Franz Mensch is an FSC®-certified and ISO certified company.

FSC® certification no.: SGSCH-COC-050190 ISO 9001:2015



Buchloe, 07.08.2023

Achim Theiler Management

Updated 07.08.2023

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Page 2/2