



EU DECLARATION OF CONFORMITY

MANUFACTURER:

SPLENDOR tekstil d.o.o.

Petrovaradinska 1a

10 000 Zagreb

Republika Hrvatska

declares that the

DEVICE:

Four-layer medical face mask with nano filter

Item number: **2101003**

Basic UDI-DI: 3858889172101003WY

Classification: The medical device has been assigned to class I, according to rule 1, Annex VIII of the Medical Device Regulation (EU 2017/745)

is in compliance to the

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017 on medical devices

and the following standards:

HRN EN ISO 13485:2016

HRN EN ISO 14971:2019

HRN EN ISO 15223-1:2016

HRN EN 14683:2019+AC:2019

ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2013

This declaration is issued under the exclusive responsibility of the manufacturer.

SPLENDOR tekstil d.o.o.

Željko Perčić, CEO

Zagreb, 20.01.2022.