

Maurissē

Maurisse Export Sp. z o.o.

ul. Chwaszczyńska 131a

81-571 Gdynia

Poland

EU Declaration of Conformity, no 1/2020



The manufacturer:

name: **Maurisse Export Sp. z o.o.**
address: ul. Chwaszczyńska 131a, 81-571 Gdynia, Poland

declare under his sole responsibility that the product:

Name: **Mund und Nasen Schutzmaske**
model: **MNS-C19**
serial number: **from 00000000/30072020 to 99999999/30122029**
product class: **I in accordance with the AnnexVIII MDR (UE) 2017/745**

meets the following essential requirements:

- Medical Devices Regulation **MDR (UE) 2017/745**,
- Regulation on registration, evaluation, authorisation and restrictions on chemicals **REACH (UE) 1907/2006**,

Complies with the requirements of the following harmonised standards:

- **EN 14683:2019+AC:2019**
- **EN ISO 13485:2016+AC:2016**
- **EN 1041:2008**
- **EN ISO 14971:2012**
- **EN ISO 15223-1:2016**
- **EN ISO 10993-1:2009+AC:2010**

This declaration applies only to the product in the state in which it was placed on the market and does not include components added by the end-user or subsequent actions or changes carried out by the end-user.

Gdynia, 10.08.2020 r.

place, date

signature

Prezes Zarządu

Maurisse Export Sp. z o.o.

Michał Iwanowski

first name, last names function

Maurisse Export Sp. z o.o.

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