

MARION

MARION Sp. z o.o.,
ul. Chwaszczyńska 131A,
81-571 Gdynia
NIP 958-13-94-151
REGON 192622037

EU Declaration of Conformity, no 4/2020



The manufacturer:

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

declares that this EU declaration of conformity was issued under the sole responsibility of the manufacturer, who declares that the product:

Name: **Medical mask**
model: **MK-1 Comfort**
serial number: from 00000000/30072020 to 99999999/30122029
product class: **I, non sterile, in accordance with the AnnexVIII MDR (UE) 2017/745**
Basic UDI-DI code:
Photograph:

meets the general safety and performance requirements of:

- Medical Devices Regulation **MDR (UE) 2017/745**,

Complies with the requirements of the following harmonized standards:

- **EN 14683:2019+AC:2019**
- **EN ISO 13485:2016+AC:2018**
- **EN 1041:2008**
- **EN ISO 14971:2012**
- **EN ISO 15223-1:2016**
- **EN ISO 10993-1:2009+AC:2010**
- **EN 62366-1:2015**

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, 26th August 2020 y.

place, date

signature

first name, last names function

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Prezes Zarządu
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Waldemar Ostrowski