

EU Declaration of Conformity, no 7/2021

The manufacturer:

name: **Marion Private Label Sp. z o.o. – s.k.**
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 INVENTI**
model: **INV001**
serial number: from **00000000/08012021** to **99999999/08012029**
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**
- **ISO 18184:2019**
- **EN ISO 13485:2016+AC:2018**
- **EN 1041:2008+A1:2013**
- **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, 8th January 2021 y.
place, date

signature

Marion Private Label Sp. z o.o. – s.k.
81-571 Gdynia, ul. Chwaszczyńska 131a
NIP 9581707124, REGON 385683704
first name, last name, function
KRS 0000831824

za komplementariusza

Michał Ostrowski

Wiceprezes Zarządu
Marion Private Label Sp. z o.o.

Michał Ostrowski