

## Declaration of Conformity form

Document #

Product: DeltriSafe+ Type II

DSM-DOC-DS+ -Rev2

Manufacturer's name:

**Deltrian Protective Equipment** 

Rue de Berlaimont, 21 A

Manufacturer's address:

6220 Fleurus

Belgium

Product type:

Surgical/medical face mask

Product:

DeltriSafe +

Model # and name (if applicable):

DeltriSafe + SURGICAL MASK 3 PLY TYPE II +

UDI - ID

5700105

GMDN:

35177

Classification:

Class I

Conformity assessment procedure:

Regulation (UE) 2017/745, Annex IV

**Deltrian Protective Equipements** 

Manufacturing site(s):

Rue de Berlaimont, 21 A

Belgium

6220 Fleurus

Notified body:

Not applicable as Class I medical devices

Notified body's ID:

Not applicable as Class I medical devices

EC Certificate(s) #

Not applicable as Class I medical devices

We declare under our sole responsibility that the product(s) specified above meet(s) the provision of the Regulation (EU) 2017/745 and its transpositions in national laws which apply to it, as well as harmonized standard EN 14683: 2019 + AC: 2019. The declaration of valid in connection with the "final inspection report" of the device

Place:

Fleurus, Belgium

Date of issue: 2021-03-03

Signature:

Jürgen Alexius

Full name:

Chief Executive Officer

COMPANY CONFIDENTIAL

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