DAMA MEDICAL

CE 1024

DECLARATION OF CONFORMITY DECLARATION OF CONFORMITY

According to Regulation (EU) 2016/425 on personal protective equipment, and according to Act 268/2014 Coll., on medical devices, in conjunction with Government Regulation No. 54/2015 Coll., on technical requirements for medical devices, in accordance with Act No. 22/1997 Coll., on technical requirements for products and Council Directive 93/42/EEC, on medical devices.

Manufacturer information:

Manufacturer:

DAMA TRADE, s.r.o.

Seat:

Dubová 642/15, 637 00 Brno, Czech Republic

Product identification data:

Title:

RESPIRATOR DAMA FFP2

Type: DAMA FFP2

Intended use:

The intended purpose is to cover the user's mouth and nose to minimize the direct transmission of infectious particles between the user and persons in his/her eye
The respirator also serves to protect the user by filtering the inhaled air

with an overall efficiency exceeding 95%.

Type: FFP2

Class of medical device:

I (non-sterile, non-measuring function)

The DAMA FFP2 Respirator is in compliance with the standard

EN 14683+AC:2019 and EN 149:2001+A1:2009.

The manufacturer declares that the properties of the above device meet all the requirements set out in CSN EN 149+A1:2009 and Regulation (EU) 2016/425, as well as Act No. 268/2014 Coll., Government Regulation 54/2015 Coll. and Directive 93/42/EEC, and that this device is safe and effective for its intended purpose. The manufacturer further declares that he has taken measures to ensure that the device placed on the market complies with the essential requirements and the manufacturer's technical documentation.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

in accordance with Regulation (EU) 2016/425 on personal protective equipment, Act No. 268/2014 Coll., on medical devices, in connection with Government Regulation No. 54/2015 Coll., on technical requirements for medical devices, in accordance with Act No. 22/1997 Coll., on technical requirements for products and Council Directive 93/42/EEC on medical devices.

Manufacturer Information:

Manufacturer:

DAMA TRADE, s.r.o.

Registered office

Dubová 642/15, 637 00 Brno, Czech Republic

Product Identification Data:

Title:

RESPIRATOR LADY FFP2

type: DAMA FFP2

Intended use:

The intended purpose is to cover the user's mouth and nose to minimize the direct transmission of infectious particulates between the user and persons around him (including patients). The respirator also serves to protect the user by filtering the inhaled air

with an overall efficiency exceeding 95%.

Type: FFP2

Class of medical device:

I (non-sterile, non-measuring function)

The Respirator DAMA FFP2 is in accordance with EN 14683+AC:2019 and EN 149:2001+A1:2009.

The manufacturer declares that the properties of the above device fulfil all the requirements laid down in standard EN 149:2001+A1:2009 and Regulation (EU) 2016/425, in Act No. 268/2014 Coll., Government Regulation 54/2015 tive for the intended purpose. The manufacturer further declares that he has taken measures to ensure compliance of the device placed on the market with the essential requirements and the manufacturer's technical documentation.

This declaration of conformity is issued under the sole responsibility

of the manufacturer.

in Brno / In Brno 5/2021

Tomas Opatřil

CEO of DAMA TRADE s.r.o.

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