

EU DECLARATION OF CONFORMITY

Issued according to Annex IX
to the Regulation (EU) 2016/425
on personal protective equipment as amended

Manufacturer:

BTL Industries Ltd.
161 Cleveland Way
Stevenage
Hertfordshire SG1 6BU
United Kingdom

Authorised representative:

BTL ITALIA S.r.l.
Via Delle Rimembranze, 10 (Linate)
20068, Peschiera Borromeo (MI)
Italy

The **BTL Industries Ltd.** issues this Declaration of Conformity under its sole responsibility and herewith declares that the product

Product Description: **Personal protective equipment against substances and mixtures which are hazardous to health and harmful biological agents**

Product Name: **BTL Respirator**
Product Model(s): **C-FIT Healthcare Respirator**

Risk Category: **Category III**
According to Annex I of Regulation (EU) 2016/425

is in conformity with requirements of the Regulation (EU) 2016/425 personal protective equipment as amended and with requirements of below listed standards:

EN 149 + A1 : 2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.

Notified Body Výzkumný ústav bezpečnosti práce, performed the EU type-examination (Module B) of above mentioned PPE and issued the EU type-examination certificate No.: **1024/E-079/2020**

the above mentioned PPE is subject to the conformity assessment procedure - conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified Body: Výzkumný ústav bezpečnosti práce, v. v. i, and bears the CE mark:



Date of Issue: 01/01/2021
Place of Issue: Stevenage

Signature on behalf of
BTL Industries Ltd.
BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU Hertfordshire
United Kingdom
Jakub Machálek
Regulatory Affairs Manager

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161 Cleveland Way
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20068, Peschiera Borromeo (MI)
Italy

The **BTL Industries Ltd.** issues this Declaration of Conformity under its sole responsibility and herewith declares that the product

Product Description: **Personal protective equipment against substances and mixtures which are hazardous to health and harmful biological agents**

Product Name: **BTL Respirator**
Product Model(s) **FLAT-FIT Healthcare Respirator**

Risk Category: **Category III**
According to Annex I of Regulation (EU) 2016/425

is in conformity with requirements of the Regulation (EU) 2016/425 personal protective equipment as amended and with requirements of below listed standards:

EN 149 + A1 : 2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.

Notified Body number 1024, Výzkumný ústav bezpečnosti práce, v. v. i, Jeruzalémská 1283/9, 110 00 Praha 1 – Nové Město, Czechia, performed the EU type-examination (Module B) of above mentioned PPE and issued the EU type-examination certificate No.: **1024/E-058/2020**

the above mentioned PPE is subject to the conformity assessment procedure - conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified Body number 1024, Výzkumný ústav bezpečnosti práce, v. v. i, Jeruzalémská 1283/9, 110 00 Praha 1 – Nové Město, Czechia and bears the CE mark:



Date of Issue: 01/01/2021
Place of Issue: Stevenage

Signature on behalf of
BTL Industries Ltd.
BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU Hertfordshire
United Kingdom
Jakub Machálek
Regulatory Affairs Manager

Occupational Safety Research Institute, v.v.i.

Jeruzalémská 1283/9, 110 52 Praha 1, Czech Republic

Notified Body 1024



EU TYPE-EXAMINATION CERTIFICATE No. 1024/E-058/2020

This EU type-examination certificate is issued to:

Manufacturer: BTL Industries, Ltd.
161 Cleveland Way Stevenage,
SG1 6BU Hertfordshire, United Kingdom

Identification number: 826

PPE product: BTL Respirator

Type: FLAT-FIT Healthcare Respirator

It is certified that the manufacturer's technical file and above mentioned PPE product have been assessed and found to be in accordance with the essential health and safety requirements of Regulation (EU) 2016/425 of the European parliament and of the Council on personal protective equipment, as recorded in Report No.1024/ZZ-052/2020, which is an integral part of this Certificate.

When examined the model was found to meet all of the relevant requirements of the appropriate harmonized standard(s):

EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. ČSN EN 149:2002+A1:2009, ČSN EN 149+A1 OPRAVA 1:2018)

The certification was performed according to the certification scheme of Regulation (EU) 2016/425 Module B.

Marking and instructions have been assessed in the Czech language only.

Certificate is valid until 23. 7. 2025.

For and on behalf of Occupational Safety Research Institute
Notified Body No. 1024:

Date of Issue: 23. 7. 2020

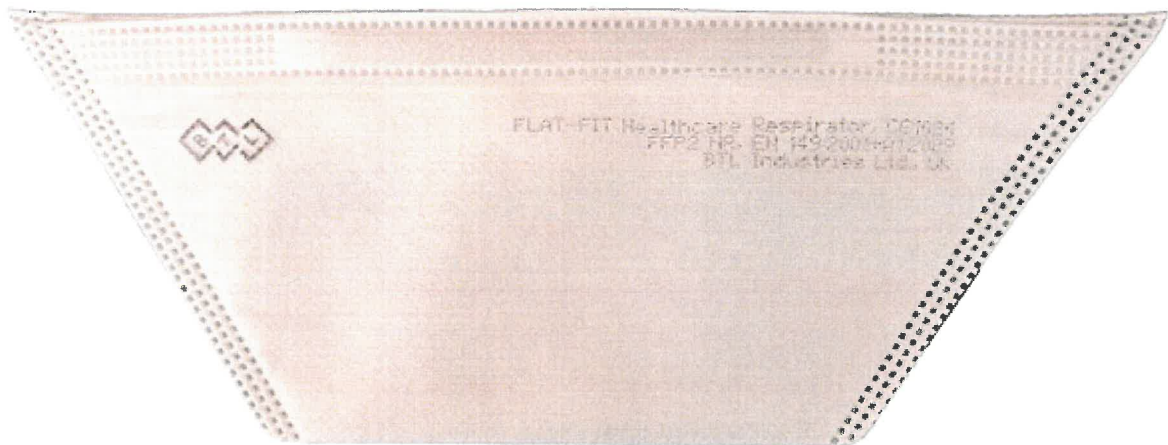


A blue ink handwritten signature, likely belonging to Ing. Jiří Tilhon, Ph.D.

Ing. Jiří Tilhon, Ph.D.

This certificate was issued in Czech and English versions. Both versions have the same validity.

Description and picture of the PPE product:



The particle filtering half mask **BTL FLAT-FIT Healthcare Respirator FFP2 NR** provides the protection of the respiratory system of a user against solid and liquid aerosols in the air in accordance with the information supplied by the manufacturer.

The product meets the class FFP2 requirements.

The product is classified in category III and shall only be used in conjunction with conformity assessment procedure Module C2 within the meaning of Regulation (EU) 2016/425.



Graphical appearance of CE mark. In the event of the involvement of a notified body in the stage of manufacturing check (category III, Module C2 or D) its distinguishing number shall be added to CE mark.

Occupational Safety Research Institute, v.v.i.

Jeruzalémská 1283/9, 110 52 Praha 1, Czech Republic
Notified Body 1024



EU TYPE-EXAMINATION CERTIFICATE No. 1024/E-079/2020

This EU type-examination certificate is issued to:

Manufacturer: BTL Industries, Ltd.
161 Cleveland Way Stevenage,
SG1 6BU Hertfordshire, Velká Británie

Identification number: 826

PPE product: BTL Respirator

Type: C-FIT Healthcare Respirator

It is certified that the manufacturer's technical file and above mentioned PPE product have been assessed and found to be in accordance with the essential health and safety requirements of Regulation (EU) 2016/425 of the European parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, as recorded in Report No.1024/ZZ-070/2020, which is an integral part of this Certificate.

When examined the model was found to meet all of the relevant requirements of the appropriate harmonized standard(s):

EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. ČSN EN 149:2002+A1:2009, ČSN EN 149+A1 OPRAVA 1:2018)

The certification was performed according to the certification scheme of Regulation (EU) 2016/425 Module B.

Marking and instructions have been assessed in the English language only.

Certificate is valid until 1. 10. 2025.

For and on behalf of Occupational Safety Research Institute
Notified Body No. 1024:



Date of Issue: 1. 10. 2020

Ing. Jiří Tílhon, Ph.D., LL.M.

This certificate was issued in Czech and English versions. Both versions have the same validity.

Description and picture of the PPE product:



The particle filtering half mask **C-FIT Healthcare Respirator** FFP2 NR provides the protection of the respiratory system of a user against solid and liquid aerosols in the air in accordance with the information supplied by the manufacturer.

The product meets the class FFP2 requirements.

The product is classified in category III and shall only be used in conjunction with conformity assessment procedure Module C2 within the meaning of Regulation (EU) 2016/425.



Graphical appearance of CE mark. In the event of the involvement of a notified body in the stage of manufacturing check (category III, Module C2 or D) its distinguishing number shall be added to CE mark.