July 30, 2020

Mr. David Chmel
BTL Industries
362 Elm Street
Marlborough, MA 01752
EUA201586

Re: Imported FFRs

Dear Mr. Chmel:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator as an authorized respirator to the June 6, 2020 Emergency Use Authorization (EUA)[1], which was issued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). We have reviewed your email and determined that the BTL Respirator model FLAT-FIT Healthcare Respirator meets the eligibility criteria in the June 6, 2020 EUA for imported, non-NIOSH approved respirators. As such, your respirator is hereby added to Exhibit 1[2] as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Exhibit 1, as described in the Scope of Authorization (Section II). As such, the respirator is authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

[1] The EUA Letter of Authorization is available at, https://www.fda.gov/media/136403/download
[2] Exhibit 1 is available at, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#exhibit1.

Importers

A. All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

B. No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.

C. Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

D. Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.

Additionally, please be advised that if your firm does not have the appropriate fluid resistance testing, the respirator should not be labeled as "surgical."

Import information can be found on the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 page. If you need to resolve entry issues for shipments, please contact 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Sincerely,

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Suzanne Schwartz, MD, MBA
Deputy Director (& Acting Office Director)
Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health

BTL Industries

EC 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

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.
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 780:2015	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages
EN ISO 14971:2012	Medical device – Application of risk management to medical devices

BTL Industries

Notified Body: Výzkumný ústav bezpečnosti práce, v. v. i, performed the EU type-examination (Module B) of above mentioned PPE and issued the EU type-examination certificate No.: XXX

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: CE 1024

Date of Issue: 23/07/2020

Place of Issue: Stevenage

Signature on behalf of
BTL Industries Ltd.

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

Lukáš Množil
Regulatory Affairs

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:

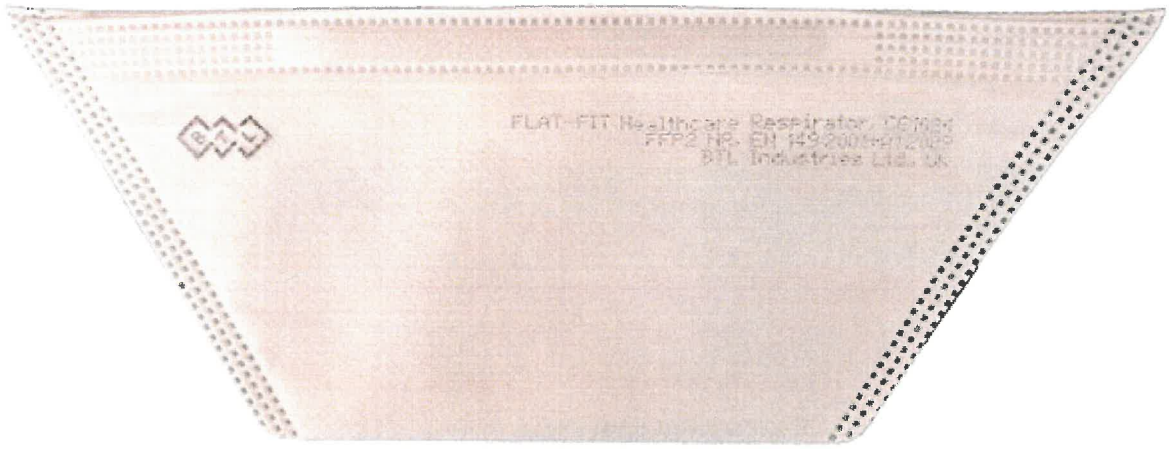
Výzkumný ústav bezpečnosti práce, v.v.i. Oznámený subjekt 1024 - Notified Body 1024 VÚBP v.v.i. Jeruzalémská 1283/9 Praha 1 Czech Republic

Date of Issue: 23. 7. 2020

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.

CE

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.