# 

# Regulatory Alert: European Union (EU) Personal Protective Equipment

April 27, 2020

## **European Union Level**

From April 26, 2020, updated export authorization requirements will be in place for personal protective equipment (PPE), now covering a reduced set of items. The new, narrower restrictions replace the previous temporary export control measures (dated 15 March 2020) and will be in place for a period of 30 days.

An export authorization is now required by the competent authorities of the member states for the export outside the EU for the following PPE items:

- Protective spectacles and visors
- Mouth-nose-protection equipment
- Protective garments only

The items in scope of the restriction can be identified by means of an 8-digit CN code. Please see Annex I for more information. The measures do not apply to the sale or movement of goods within the EU, including the United Kingdom (UK).

Exports to the Republic of Albania, Andorra, Bosnia and Herzegovina, EU overseas countries and territories, Faeroe Islands, Gibraltar, the Republic of Iceland, Kosovo, Liechtenstein, Montenegro, Norway, North Macedonia, San Marino, Serbia, Switzerland, and the Vatican are exempted.

Review Clause: The regulation includes a review clause that will allow the European Commission to adjust at any time the product scope or the duration of the provisions in light of possible new developments.

Export Licensing Application Responsibilities and Decisions: Exporters are responsible for identifying any shipments with articles in scope of these regulations, for applying at their own expense for the licenses, and for providing FedEx/TNT with all necessary information. Applications for an export authorization can be made to the relevant EU member state using the form set out in Annex II to the Implementing Regulation. EU member state authorities are under an obligation to process applications for export authorizations within 5 working days. The details of the competent national authorities can be found here.

Export authorizations will be granted only where the shipment in question does not pose a threat to the availability of these goods on the market of the member state in question or elsewhere in the EU. In line with the Commission's efforts to match supply and demand in the EU, the regulation obliges member states to consult the Commission when assessing whether to issue an export authorization. The Commission shall issue an opinion within 48 hours from the receipt of the request. In the spirit of transparency, the regulation also requires member states to report to the Commission on their authorizations granted and refused and commits the Commission to report publicly on these developments.

## Additional National Restrictions for Exports and Imports

In addition to the EU Regulation, some EU member states and third countries are implementing additional national restrictions, by means of which:

- Medicines and medical equipment are being made subject to an export ban
- Movements within the EU customs territories are now being restricted too
- Imports of PPE, medicines and medical equipment are now subject to new requirements applying to different types of imports (commercial imports of masks, diagnostic kits or others, versus private individual imports of masks in small quantities)

### **CE Marking and Conformity to EU Standards**

All existing requirements on items being imported into the EU conforming to the applicable EU safety, health and environmental protection requirements remain in place. To avoid delays due to inspections and potential seizure of commodities:

- 1. Foreign exporters **must check with their importers in the EU** in advance if their products require conformity to EU quality standards and additional documentation demonstrating it.
- For items subject to CE Marking requirements, copies of the EU Declaration of Conformity in the English language must be provided at the time of shipping.
- 3. For items requiring further import approvals (for example, extraordinary approvals issued by the national health authorities), copies must be provided at the time of shipping.

# Relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of COVID-19

On April 3, 2020, the EU issued a <u>Decision</u> granting relief from import duties and a VAT exemption on importation for goods needed to combat the effects of the COVID-19 outbreak, subject to conditions.

In order to qualify, the goods must be imported by state organizations or approved charitable or philanthropic organizations. In addition, they must be distributed or made available free of charge to persons affected by or involved in fighting COVID-19. The granting of these exemptions is backdated to January 30, 2020, and valid until July 31, 2020.

Currently, there is no publicly available list of competent authorities. Please reach out to your local customs authority for more information.

Guidance Note published by the European Commission: The EU has also published Guidelines for border management measures to protect health and ensure the availability of goods and essential services. Please review this document for more information on the obligations that EU member state authorities must observe during the COVID-19 pandemic to ensure the free circulation of goods and maintain the integrity of the EU single market.

Additional Info: The World Customs Organization has published a <u>table with HS classification</u> details for the most common Covid-19 medical supplies.

**Legal Basis:** Commission Implementing Regulation (EU) 2020/568 of 23 April 2020 making the exportation of certain products subject to the production of an export authorization.

**Timeline for Implementation:** Temporary restriction that is in effect for 30 days. May be adjusted in scope and/or duration in light of new developments.

ANNEX I – LIST OF PROTECTIVE EQUIPMENT (in scope of Commission Implementing Regulation (EU) 2020/568 of April 23, 2020

Category	Description	CN Codes
Protective spectacles and visors	Protection against potentially infectious material     Encircling the eyes and surroundings     Compatible with different models of filtering facepiece (FFP) masks and facial masks     Transparent lens     Reusable (can be cleaned and disinfected) or singleuse items     Can seal the skin of the face	ex 9004 90 10 ex 9004 90 90
Mouth-nose- protection equipment	Masks for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material     Reusable (can be cleaned and disinfected) or singleuse items     Can include a face shield     Whether or not equipped with a replaceable filter	ex 6307 90 98 ex 9020 00 00
Protective garments	— Non-sterile garment (e.g., gown, suit) for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material — Reusable (can be cleaned and disinfected) or single-use items	ex 3926 20 00 ex 4015 90 00 ex 6113 00 ex 6114 ex 6210 10 10 ex 6210 10 92 ex 6210 10 98 ex 6210 20 00 ex 6210 30 00 ex 6210 40 00 ex 6210 50 00 ex 6211 32 10 ex 6211 32 90 ex 6211 33 10 ex 6211 33 90 ex 6211 39 00 ex 6211 42 10 ex 6211 42 90 ex 6211 43 90 ex 6211 43 90 ex 6211 49 00 ex 9020 00 00

### References:

List of competent authorities in member states

https://trade.ec.europa.eu/doclib/docs/2020/march/tradoc\_158674.pdf

Guidance note published by the European Commission

https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/european-agendamigration/20200316 covid-19-guidelines-for-border-management.pdf

HS Classification details for the most common COVID-19 medical supplies <a href="http://www.wcoomd.org/en/media/newsroom/2020/april/joint-wco-who-hs-classification-list-for-covid">http://www.wcoomd.org/en/media/newsroom/2020/april/joint-wco-who-hs-classification-list-for-covid</a> 19-medical-supplies-issued.aspx

Commission implementing regulation (EU) 2020/402 of March 14, 2020 https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32020R0402

Commission decision of March 4, 2020 on relief duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020 <a href="https://ec.europa.eu/taxation\_customs/sites/taxation/files/03-04-2020-import-duties-vat-exemptions-on-importation-covid-19.pdf">https://ec.europa.eu/taxation\_customs/sites/taxation/files/03-04-2020-import-duties-vat-exemptions-on-importation-covid-19.pdf</a>

Commission implementing regulation (EU) 2020/568 of April 23, 2020 <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L..2020.129.01.0007.01.ENG&toc=OJ:L:2020:129:TOC">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L...2020.129.01.0007.01.ENG&toc=OJ:L:2020:129:TOC</a>

European Commission - Coronavirus: Commission adjusts export authorization scheme for personal protective equipment to suit current needs https://trade.ec.europa.eu/doclib/press/index.cfm?id=2139