MEDICAL EQUIPMENT IMPORT (PPE/MD)

- Masks
- Gloves
- Glasses
- Thermometers





Non-surgical protection mask FFP1/FFP2/FFP3 type

Product type: PPE

(Personal Protection Equipement)

HS code: 6307909810

Import duty rates: 6,3%

Regulation:

Regulation (EU) n ° 2016/425 of March 9, 2016 relating to protective equipment

Documents to present:

1- Declaration of conformity drawn up by the manufacturer, his authorized representative or the importer, in French or in English, including the name and address of the manufacturer, the product reference, the reference to the reference or to the text on which the CE standard is based or the equivalent foreign standard.

2- Certificate of conformity validated by a notified body for the product

Equivalence of standards: YES

EU Equivalence of standards:



- 1- Declaration of conformity.
- 2- Valid report from a laboratory accredited by the issuing State.
- 3 Proof of filing (+ acknowledgment of receipt) of the EU certificate request for conformity.

No EU standards or equivalence

Documents to present:

- 1 Declaration of conformity
- 2 Valid report from a laboratory accredited by the issuing State
- 3 Any other document likely to give a ruling (photographs, test reports)

Find a notified organization



Tolerance:

Referral to APAVE (PPE procedure): it is accepted that proof of referral to APAVE by the importer suffices to consider that the conformity assessment procedures have been initiated.



Surgical Mask

Product type: MD (Medical Device)

HS code: 4818901000

Import duty rates: 0%

Regulation:

Council Directive 93/42 / EEC of June

14, 1993

Documents to present:

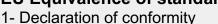
1 - Affixing the CE marking

2 - Presentation on request from the service: EC declaration of conformity and technical file or the EC type examination certificate for products affected by the Medical Devices regulation.



Equivalence of standards: YES

EU Equivalence of standards:



2- Test report



Documents to present:

- 1 Declaration of conformity
- 2 Valid report from a laboratory accredited by the issuing State
- 3 Any other document likely to give a ruling (photographs, test reports)

Find a notified organization



.pdf DM





Plastic visors

Product type: PPE

(Personal Protection Equipement)

HS code: 3926909790

Import duty rates: 6,5%

Regulation:

Regulation (EU) n ° 2016/425 of March 9, 2016 relating to protective equipment

Documents to present:

1- Declaration of conformity drawn up by the manufacturer, his authorized representative or the importer, in French or in English, including the name and address of the manufacturer, the product reference, the reference to the reference or to the text on which the CE standard is based or the equivalent foreign standard.

2- Certificate of conformity validated by a notified body for the product

Equivalence of standards: YES

DECLARATION OF CONFORMITY

EU standard in







Surgical gowns

Product type: MD (Medical Device)

HS code: 6210109200

Import duty rates: 12%

Regulation:

Council Directive 93/42 / EEC of June

14, 1993

Documents to present:

1 - Affixing the CE marking

2 - Presentation on request from the service: EC declaration of conformity and technical file or the EC type examination certificate for products affected by the Medical Devices regulation.







Protective glasses with plastic lenses

Product type: PPE

(Personal Protection Equipement)

HS code: 9004901000

Import duty rates: 2,9%

Regulation:

Regulation (EU) n ° 2016/425 of March 9, 2016 relating to protective equipment

Documents to present:

1- Declaration of conformity drawn up by the manufacturer, his authorized representative or the importer, in French or in English, including the name and address of the manufacturer, the product reference, the reference to the reference or to the text on which the CE standard is based or the equivalent foreign standard.

2- Certificate of conformity validated by a notified body for the product

DECLARATION OF CONFORMITY

EU standard in







Protective glasses with non plastic lenses

Product type: PPE

(Personal Protection Equipement)

HS code: 9004909000

Import duty rates: 2,9%

Regulation:

Regulation (EU) n ° 2016/425 of March 9, 2016 relating to protective equipment

Documents to present:

1- Declaration of conformity drawn up by the manufacturer, his authorized representative or the importer, in French or in English, including the name and address of the manufacturer, the product reference, the reference to the reference or to the text on which the CE standard is based or the equivalent foreign standard.

2- Certificate of conformity validated by a notified body for the product

DECLARATION OF CONFORMITY







Plastic gloves

Product type: PPE

(Personal Protection Equipement)

HS code: 3926200000

Import duty rates: 6,5%

Regulation:

Regulation (EU) n ° 2016/425 of March 9, 2016 relating to protective equipment

Documents to present:

1- Declaration of conformity drawn up by the manufacturer, his authorized representative or the importer, in French or in English, including the name and address of the manufacturer, the product reference, the reference to the reference or to the text on which the CE standard is based or the equivalent foreign standard.

2- Certificate of conformity validated by a notified body for the product



DECLARATION OF CONFORMITY

EU standard in





Surgical gloves (not reusable)

Product type: MD (Medical Device)

HS code: 4015110000

Import duty rates: 2%

Regulation:

Council Directive 93/42 / EEC of June

14, 1993

Documents to present:

1 - Affixing the CE marking

2 - Presentation on request from the service: EC declaration of conformity and technical file or the EC type examination certificate for products affected by the Medical Devices regulation.







Disposable powder-free chemical gloves (not reusable)

Product type: PPE

(Personal Protection Equipement)

HS code: 4015110000

Import duty rates: 2,7%

Regulation:

Regulation (EU) n ° 2016/425 of March 9, 2016 relating to protective equipment

Documents to present:

1- Affixing of CE marking

2- Declaration of conformity drawn up by the manufacturer, his authorized representative or the importer, in French or in English, including the name and address of the manufacturer, the product reference, the reference to the reference or to the text on which the CE standard is based or the equivalent foreign standard.

3- Certificate of conformity validated by a notified body for the product

DECLARATION OF CONFORMITY

EU standard in







Digital or infrared thermometers

Product type: MD (Medical Device)

HS code: 9025190090

Import duty rates: 0%

Regulation:

Council Directive 93/42 / EEC of June

14, 1993

Documents to present:

1 - Affixing the CE marking

2 - Presentation on request from the service: EC declaration of conformity and technical file or the EC type examination certificate for products affected by the Medical Devices regulation.



