

MEDICAL EQUIPMENT IMPORT (PPE/MD)

- Masks
- Gloves
- Glasses
- Thermometers





Product:

Non-surgical protection mask
FFP1/FFP2/FFP3 type

Product type: PPE

(Personal Protection Equipment)

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



[.pdf PPE](#)

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.



Product:
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:

1- Declaration of conformity

2- Test report



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)

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[.pdf DM](#)



Product:
Plastic visors

Product type: PPE
(Personal Protection Equipment)

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

I, M General Manager of the company....

.....Confirm an import... from for

..... Use, manufactured by the company

Under the reference Invoice number

quantity adopt the UE standardIncluding test report

number is joined withThis certificate is issued to assert to whom it may concern.

Stamp and date signature.....





Product:
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.





Product:
Protective glasses with plastic lenses

Product type: PPE
(Personal Protection Equipment)

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



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Product:

Protective glasses with non plastic lenses

Product type: PPE

(Personal Protection Equipment)

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.

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Product:
Plastic gloves

Product type: PPE
(Personal Protection Equipment)

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



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Product:
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.





Product:

Disposable powder-free chemical gloves (not reusable)

Product type: PPE

(Personal Protection Equipment)

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



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Product:
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.

