MANUFACTURERS AGREEMENT PPE OEM/OBL - REGULATION (EU) 2016/425

Placing on the market of products made by another manufacturer marked/labelled under their own name

1.0 Manufacturer’s data

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| Original manufacturer of the certified product | |  | Manufacturer that marks/labels under itsown brand name | |
| Company |  |  | Company |  |
| Tax code/VAT n. |  |  | Tax code/VAT n. |  |
| Registered office |  |  | Registered office |  |
| Headquarters |  |  | Headquarters |  |
| Contact ref |  |  | Contact ref |  |
| Phone |  |  | Phone |  |
| e-mail |  |  | e-mail |  |
| Hereinafter in the document identified as: OEM Manufacturer **[[1]](#footnote-1)** | |  | Hereinafter in the document identified as: Manufacturer OBL **[[2]](#footnote-2)** | |

2.0 Identification of the models covered by OEM-OBL contract

| OEM Type certified | OEM variants certified | OBL Type | OBL variants |
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3.0 OEM Manufacturer's type certificates

| OEM Type certified | Cat. | Technical file | EU type-examination Certificate | Issue date | Expiry date |
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3.1 Certificates of Type conformity for marking of category III PPE – OEM Manufacturer

| OEM [[3]](#footnote-3) Type certificate | Module C2/D Certificate | Issue date | Expiry date |
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4.0 Joint declarations of OEM and OBL manufacturers on certified products

The undersigned, Fiscal code      , born in      , on      , residing in      , street      , no.      , as legal Representative of the OEM manufacturer     , being aware of the provisions of art. 46 and 47 of the Italian Presidential Decree no. 445 on 28.12.2000 concerning declarations, and art. 76 of the Italian Presidential Decree no. 445 on 28.12.2000 and art. 495 of the Italian Penal Code concerning the event of false declarations, declare under his/her own responsibility that:

* the products described in paragraph 2.0, whose references are given in paragraph 3.0, meet the conformity requirements set out into Regulation (EU) 2016/425;
* they are manufactured in conformity with the Type(s) described in the technical file(s) referred to in the same paragraph 3.0;
* when they belong to the risk category III as described in Annex I of the aforementioned Regulation, they meet the additional requirements of the conformity assessment procedures indicated in the certificates referred to in paragraph 3.1.

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| Place and date: |
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| Name Surname of the legal representative, signature and stamp of the OEM company |

The undersigned      , fiscal code      , born in      , on      , residing in      , street      , no.      , as legal Representative of the OBL manufacturer     , aware of the provisions of art. 46 and 47 of the Italian Presidential Decree no. 445 of 28.12.2000 concerning declarations and art. 76 of the Italian Presidential Decree no. 445 of 28.12.2000 and art. 495 of the Italian Penal Code concerning the event of false declarations, declares under his own responsibility that:

* He/She will not make any changes to the products described in paragraph 2.0 made by the OEM manufacturer      ,
* He/She will market under his/her own name and trademark, except for what related to the aspects regarding the EU marking however performed in compliance with article 16 of EU Regulation 2016/425.

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| Place and date: |
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| Name Surname of the legal representative, signature and stamp of the OBL company |

5.0 Terms and conditions for issuing of the EU type-examination Certificate to the OBL manufacturer (Module B)

Following to the submission of the application form and the successful conduct of the activities envisaged by the conformity assessment procedure according to Annex V of Regulation (EU) 2016/425, MTIC InterCert S.r.l. will issue a EU type-examination Certificate (Module B) to the OBL manufacturer.

The issue of the EU type-examination Certificate to the OBL manufacturer is subject to assessment by MTIC InterCert S.r.l. of the existence of the EU type-examination Certificate issued to the OEM manufacturer and of its validity, as well as the assessment of compliance of the product and of the technical documentation provided by the OBL manufacturer as referred to in Annex III of Regulation (EU) 2016/425 possibly collected in the form of a technical file, and in particular the following documents:

* Instructions and manufacturer's information referred to in point 1.4 of Annex II of Regulation (EU) 2016/425
* EU Declaration of Conformity according to the structure set out into Annex IX of Regulation (EU) 2016/425
* Model of the marking that will be used on the products including the provisions of paragraphs 5 and 6 of Article 8 of Regulation (EU) 2016/425

The conformity assessment of the product shall be carried out in accordance with the procedures defined by the notified Body.

The Certificate will be valid under the following conditions:

* The expiry date of the Certificate issued by MTIC InterCert S.r.l. to the OBL manufacturer will be consistent with the expiry date of the corresponding EU type-examination Certificate issued to the OEM manufacturer as represented in paragraph 3.0. For this reason, the validity of the EU type-examination Certificate obtained by the OBL manufacturer following the first certification may be less than 5 years, as well as per the subsequent renewals.
* The reference to the number of the EU type-examination Certificate issued to the OEM manufacturer (paragraph 2.0), which refers to the product to be certified on behalf of the OBL manufacturer, will not be indicated on the EU type-examination Certificate issued to the OBL manufacturer, anyway it will be recorded in the official documentation of the Body as provided for the review of the certification procedure and the decision on it (Resolution).
* The validity of the EU type-examination Certificate issued to the OBL manufacturer is subject to the validity of the EU type-examination Certificate issued to the OEM manufacturer (paragraph 3.0), as stated and accepted in paragraph 8.0.

MTIC InterCert S.r.l. will not issue to the OBL manufacturer EU type-examination Certificates for products not listed in paragraph 2.0 and/or with reference to EU type-examination Certificates issued to the OEM manufacturer which are not listed in paragraph 3.0.

The OBL Manufacturer shall submit an application form for each type of product (model) listed in paragraph 2.0. The application shall be extended to all variants of the product and presented on the documental form in use to the Body.

The OBL manufacturer accepts the conditions set out into this clause.

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| Place and date: |
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| Name Surname of legal representative, signature and stamp of the OBL company |

6.0 Terms and conditions for the conformity assessment to Type for the OBL manufacturer (Module C2)

The following applies only to the personal protective equipment which in paragraph 3.0 have been declared to belong to category III by the OEM manufacturer.

Following to the submission of the application form and the successful conduct of the activities envisaged by the conformity assessment procedure according to Annex VII of Regulation (EU) 2016/425, MTIC InterCert S.r.l. will issue a Certificate of conformity to Type (Module C2) to the OBL manufacturer.

The issue of the certificate (Module C2) to the OBL manufacturer is subject to verification by MTIC InterCert S.r.l. of the existence of a valid EU type-examination Certificate issued to the OEM manufacturer, as well as assessment of the technical documentation provided by the OBL manufacturer as referred to in Annex VII of Regulation (EU) 2016/425 and the outcome of tests conducted to verify the homogeneity of production.

The tests are carried out on the products manufactured at the production sites indicated to the Body by the OBL manufacturer on the application form. These production sites must be present in the certificate of conformity to type (Module C2) issued to the OEM manufacturer.

The Certificate will be valid under the following conditions:

* The expiry date of the Certificate issued by MTIC InterCert S.r.l. to the OBL manufacturer will be consistent with the expiry date of the corresponding Certificate (Module C2) issued to the OEM manufacturer as represented in paragraph 3.1. For this reason, the validity of the Certificate obtained by the OBL manufacturer following the first certification may be shorter than the duration indicated in the Certification Rules adopted by the Body for the same, as well as per the subsequent renewals.
* The reference to the number of the Certificate (Module C2) issued to the OEM manufacturer (paragraph 3.1), which refers to the product to be certified on behalf of the OBL manufacturer, will not be indicated on the Certificate (Module C2) issued to the OBL manufacturer, anyway it will be recorded in the official documentation of the Body as provided for the review of the certification procedure and the decision on it (Resolution).
* The validity of the Certificate (Module C2) issued to the OBL manufacturer is subject to the validity of the Certificate (Module C2) issued to the OEM manufacturer (paragraph 3.1), as stated and accepted in paragraph 8.0.
* A production record listing the products marked by the OBL manufacturer and containing information concerned with the traceability of the documentation of the products by the same manufacturer shall be made available and be continuously updated.

MTIC InterCert S.r.l. will not issue to the OBL manufacturer certificates (Module C2) for products not listed in paragraph 2.0 and/or with reference to certificates (Module C2) issued to the OEM manufacturer which are not listed in paragraph 3.1.

The OBL Manufacturer shall submit an application form for each type of product (model) listed in paragraph 2.0. The application must be extended to all variants of the product and presented on the documental form in use by the Body.

The OBL manufacturer accepts the conditions set out into this paragraph.

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| Place and date: |
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| Name Surname of legal representative, signature and stamp of the OBL company |

*6.1 Terms and conditions for the conformity assessment to Type for the OBL manufacturer (Module D)*

The following applies only to personal protective equipment which in paragraph 3.0 have been declared to belong to category III by the OEM manufacturer.

Following to the submission of the application form and the successful conduct of the activities envisaged by the conformity assessment procedure according to Annex VIII of Regulation (EU) 2016/425, MTIC InterCert S.r.l. will issue a Certificate of conformity to Type (Module D) to the OBL manufacturer.

The issue of the certificate (Module D) to the OBL manufacturer is subject to verification by MTIC InterCert S.r.l. of the existence of a valid EU type-examination Certificate issued to the OEM manufacturer, and of verification of the validity of the same Certificate; it is as well subject to the verification that the quality system set up and adopted by the OEM manufacturer also applies to the Type that is subject of the application for certification submitted by the OBL manufacturer, and that the same is also applied in the production sites indicated to the Body by the OBL manufacturer on the application form. These production sites must be present in the certificate of conformity to type (Module D) issued to the OEM manufacturer.

Product conformity assessment will be carried out in accordance with the procedures defined by the Body.

The certification, surveillance and renewal activity, envisaged by the conformity assessment procedure of Annex VIII of Regulation (EU) 2016/425 (Module D), may involve at least:

* the verification of the drafting and continuous updating of a production record listing the products marked by the OBL manufacturer and containing information concerned with the traceability of the documentation of the products by the same manufacturer
* the verification of the procedure for managing products in stock
* the verification of the storage conditions of the products covered by the certification at the sites where they are stored.

The Certificate will be valid under the following conditions:

* The expiry date of the Certificate issued by MTIC InterCert S.r.l. to the OBL manufacturer will be consistent with the expiry date of the corresponding Certificate (Module D) issued to the OEM manufacturer as represented in paragraph 3.1. For this reason, the validity of the Certificate obtained by the OBL manufacturer following the first certification may be shorter than the duration indicated in the Certification Rules adopted by the Body for the same, as well as per the subsequent renewals.
* The reference to the number of the Certificate (Module D) issued to the OEM manufacturer (paragraph 3.1), which refers to the product to be certified on behalf of the OBL manufacturer, will not be indicated on the Certificate (Module D) issued to the OBL manufacturer, anyway it will be recorded in the official documentation of the Body as provided for the review of the certification procedure and the decision on it (Resolution).
* The validity of the Certificate (Module D) issued to the OBL manufacturer is subject to the validity of the Certificate (Module D) issued to the OEM manufacturer (paragraph 3.1), as stated and accepted in paragraph 8.0.
* A production record listing the products marked by the OBL manufacturer and containing information concerned with the traceability of the documentation of the products by the same manufacturer shall be made available and be continuously updated.

MTIC InterCert S.r.l. will not issue to the OBL manufacturer certificates (Module D) for products not listed in paragraph 2.0 and/or with reference to certificates (Module D) issued to the OEM manufacturer which are not listed in paragraph 3.1.

The OBL Manufacturer shall submit an application form for each type of product (model) listed in paragraph 2.0. The application must be extended to all variants of the product and presented on the documental form in use by the Body.

The OBL manufacturer accepts the conditions set out into this paragraph.

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| Place and date: |
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| Name Surname and signature of the legal representative of the OBL company |

7.0 Offer for the certification services and Rules

The conformity assessment services necessary for issuing a EU type-examination Certificate following the positive outcome of the assessment will be the subject of a technical and economic offer that MTIC InterCert S.r.l. will issue on the basis of the data included in this document.

Following the acceptance of the offer that constitutes a contract for the services contained therein, the OBL Manufacturer shall submit an application form to the Body in which it shall indicate the same conformity assessment procedures adopted by the OEM manufacturer. The OEM and the OBL manufacturer declare that the products described in paragraph 2.0 of this document are covered by the OEM-OBL commercial contract       signed by both on      .

MTIC InterCert S.r.l. applies the Certification Regulation "RG-PC-DPI-01-01" in its latest revision. The regulation is available on the Body's website.

8.0 Commitments and declarations

The undersigned, Fiscal code      , born in      , on      , residing in      , street      , no.      , as legal Representative of the OEM manufacturer     , being aware of the provisions of art. 46 and 47 of the Italian Presidential Decree no. 445 on 28.12.2000 concerning declarations, and art. 76 of the Italian Presidential Decree no. 445 on 28.12.2000 and art. 495 of the Italian Penal Code concerning the event of false declarations, declare under his/her own responsibility:

* to accept and approve the contents of this document
* that the PPE identified in paragraph 2.0 of this document and supplied to the OBL are the same as the types covered by the EU type-examination Certificates identified in paragraph 3.0, that they are manufactured in accordance with the technical file indicated in the same paragraph, with the exception of their marking, user’s information and labelling plan.
* to inform the OBL manufacturer of any suspensions, revocations, expirations of the EU type-examination Certificate or of waiver of the same.
* for PPE declared in Category III in paragraph 3.0 of this document, to inform the OBL manufacturer of any suspension, revocation, deadline, or waivers of the same EU type-examination Certificates (Module C2 and/or Module D), depending on the conformity of production assessment procedure adopted.
* to provide the OBL manufacturer with the technical documentation described in paragraphs 5.0 and 6.0 of this document, so that he can submit it to the Body, on his own behalf, together with the application form according to the conformity assessment procedure described in Annex V (Module B) and subsequently, in the case of Category III PPE, for the conformity assessment procedure described in Annex VII (Module C2) or the conformity assessment procedure described in Annex VIII (Module D).
* to inform the Body and the OBL manufacturer of any changes it intends to make to the PPE covered by the OEM-OBL contract as identified in paragraph 2.0 of this document before proceeding to manufacture the modified product
* to report to the OBL manufacturer and the Body about any complaint it may have received regarding the PPE covered by the OEM-OBL contract as identified in paragraph 2.0
* to report to the OBL manufacturer and to the Body about any accident involving the PPE covered by the OEM-OBL contract as identified in paragraph 2.0

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| Place and date: |
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| Name Surname of legal representative, signature and stamp of the OEM company |

The undersigned, Fiscal code      , born in      , on      , residing in      , street      , no.      , as legal Representative of the OBL manufacturer     , being aware of the provisions of art. 46 and 47 of the Italian Presidential Decree no. 445 on 28.12.2000 concerning declarations, and art. 76 of the Italian Presidential Decree no. 445 on 28.12.2000 and art. 495 of the Italian Penal Code concerning the event of false declarations, declare under his/her own responsibility:

* to accept and approve the contents of this document
* to be aware of the responsibilities arising from being identified as the manufacturer of the products listed in paragraph 2.0 under "OBL Type" and "OBL variants" as listed and described in Regulation (EU) 2016/425 and applicable EU legislation.
* not to make any changes to the PPE covered by the OEM-OBL contract as identified in paragraph 2.0 of this document, also following recognition of the EU type-examination Certificate issued by the Body
* to report the OEM manufacturer and to the Body about any complaint it may have received regarding the PPE covered by the OEM-OBL contract as identified in paragraph 2.0
* to report the OEM manufacturer and the to Body about any accident involving the PPE covered by the OEM-OBL contract as identified in paragraph 2.0
* to take charge of the drafting of EU Declaration of Conformity as regard to PPE that it will place on the market under its own name and trademark, in accordance with the requirements set by Regulation (EU) 2016/425 and of updating the production records as well as the traceability documentation of the products sold.
* to interrupt the sale of the PPE when the OEM communicates the suspension, expiry, revocation or waiver of related EU type-examination Certificate/s, and for Category III PPE, also for the certificates related to the conformity assessment procedure set out into Annex VII (Module C2) or the conformity assessment procedure set out into Annex VIII (Module D).
* that it is aware that the EU type-examination Certificate it will obtain from the Body as OBL manufacturer will have the same expiry date as the EU type-examination Certificate obtained by the OEM manufacturer and that its validity will lapse together with the one of the OEM following expiry, waiver, revocation or temporary suspension of the certification. The same shall apply to certificates of conformity to Type as established in the conformity assessment procedure set out in Annex VII (Module C2) or conformity assessment procedure set out in Annex VIII (Module D).
* that it has nothing to claim from MTIC InterCert S.r.l. if for any reason the Body will notify to the OBL about any expiry, revocation or temporary suspension of any certification issued to the OBL as a consequence of expiry, waiver, revocation or temporary suspension of the certification issued to the OEM
* to have nothing to claim from MTIC InterCert S.r.l. if for any reason the body should communicate to the OBL any expiry, revocation or temporary suspension of the certification issued to the OBL in case the OBL does not provide evidence of compliance with the requirements applicable to the certification issued to it by MTIC InterCert S.r.l., for aspects that fall under the responsibility of the OBL.
* to cease the sale of PPE if the OEM communicates the finding of potential dangers for the users of the PPE.

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| Place and date: |
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| Name Surname of legal representative, signature and stamp of the OBL company |

9.0 Final conditions and acceptance of the contents of the Agreement

For the purposes of Regulation (EU) 2016/425, the OBL manufacturer is the manufacturer of the PPE marked and sold under its own name.

With regard to this Agreement and its contents, MTIC InterCert S.r.l.:

* together with the certificates issued to the OBL manufacturer, keeps a copy of the certificates issued to the OEM manufacturer.
* verifies during production the data relating to the OBL manufacturer, marking, technical documentation (this may require surveillance at the headquarters of the OBL manufacturer)
* If the PPE covered by the contract refer to a EU type-examination Certificate issued by another Body, MTIC, without prejudice to the adoption of practices considered to be suitable for acquiring of information relating to technical documentation, certification, etc. on the premises of the OEM manufacturer, it will assess the most appropriate methods for verifying the production process according to the assessment procedure requested by the OEM manufacturer and by the OBL manufacturer, not excluding the possibility of repeating one or more of the test and checks provided for by the procedure for assessing conformity of the Type as per Annex V of Regulation (EU) 2016/425 (Module B) before the issue of the EU type-examination Certificate to the OBL manufacturer.
* It will keep track of cross references between the certificates issued to the OEM manufacturer and the ones issued to the OBL manufacturer even if it is decided not to make those OEM manufacturer references explicit on certificates issued to the OBL manufacturer.

For all other conditions and cases not mentioned in this document MTIC InterCert S.r.l. will adopt what is indicated in the certification regulation "RG-PC-DPI-01-01" in its last revision. The regulation is available on the Body’s website.

The Body, the OEM manufacturer and the OBL Manufacturer agree that this agreement should be revised should any regulatory and/or legislative changes invalidate one or more of its contents.

This document has been drafted in Italian language and in English language. The Body, the OEM manufacturer and the OBL manufacturer agree and approve that should any dispute on terms or contents be raised, the trusted text is the Italian one.

For acceptance of the conditions set out in the paragraphs of this document.

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| Place and date: |  |  |
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| Name Surname of legal representative, signature and stamp of the OEM company |  | Name Surname of legal representative, signature and stamp of the company OBL |

1. OEM: Original manufacturer of the certified product [↑](#footnote-ref-1)
2. OBL: Manufacturer branding products certified by the OEM manufacturer under its own name on the basis of a contract (Own brand labeller). [↑](#footnote-ref-2)
3. Enter the references of the Type of PPE in Category III in paragraph 3.0. It is not permitted to insert references other than those in paragraph 3.0. [↑](#footnote-ref-3)