

To:
DOLOMITICERT S.C.A.R.L.
Zona Industriale Villanova, 7/A
32013 Longarone BL – ITALY

**APPLICATION FOR SUPERVISED PRODUCT CHECKS AT
RANDOM INTERVALS**

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for category III Personal Protective Equipment (PPE)

in compliance with

**Regulation (EU) 2016/425 of the European Parliament and the
Council of 9 March 2016**

(Module C 2)

**N.B.: if DOLOMITICERT has not performed the EU type-examination, the following documentation
shall be attached to this application:**

(The blanks in this page must be filled in by DOLOMITICERT staff)

Technical Documentation	<input type="checkbox"/>
Copy of the EU type-examination Certificate	<input type="checkbox"/>



Manufacturer: *Real Care srl*
 Application for supervised product checks at random intervals (Module C 2) –
 Equipment: *FFP2 anti-dust filtering half mask Model : L4*

IDENTIFICATION DATA

MANUFACTURER [1]

Company name	REAL CARE SRL
Legal Headquarters	VIA DEGLI INVENTORI 6 – 41018 S.CESARIO S/P (MO) Italy
Operative Headquarters	VIA DEGLI INVENTORI 6 – 41018 S.CESARIO S/P (MO) Italy
Legal Representative	SIG. ROBERTO CALANCA
Telephone	059/5187083
Fax	-
Company Contact Person	SIG. MOHAMED S. ACHIK
Role	SALES DEPARTMENT
Telephone	059/5187051
Fax	-
E - @ MAIL	DIREZIONE@REALCARESRL.IT
Manufacturing Unit	VIA DEGLI INVENTORI 6 – 41018 S.CESARIO S/P (MO) Italy
Manufacturing Unit Headquarter	VIA DEGLI INVENTORI 6 – 41018 S.CESARIO S/P (MO) Italy
Telephone	059/5187051

[1] Any change in the above mentioned data must be promptly communicated to the notified Body

AUTHORIZED REPRESENTATIVE OR LEGAL REPRESENTATIVE IN THE EUROPEAN UNION [1] [2]

Company Name	-
Legal Headquarter	-
Legal Representative	-
Company Contact Person	-
Role	-
Telephone	-
Fax	-

[1] Any change in the above-mentioned data must be promptly communicated to the notified Body

[2] Please enclose assignment letter signed by the manufacturer

Product – basE model

Type of PPE :	FFP2 ANTI-DUST FILTERING HALF MASK
Field of application :	RESPIRATORY TRACT PROTECTION WITH THE EXCEPTION OF THOSE INTENDED FOR ESCAPE
Trade-mark :	KARINA
Identification code /Model name:	L4
Reference harmonized standard or technical specification:	EN 149:2001+A1:2009
EU type-examination certificates in existence:	2163-PPE-1785 ISSUED ON 14/12/2020
Notified body which issued the EU type-examination Certificate:	UNIVERSAL CERTIFICATION N.B. 2163

PRODUCT - VARIANTS

Variants of the basic model :	-
Identification code:	-



CONTRACT

Between

DOLOMITICERT S.C.A.R.L.
Loc. Villanova, 7/A – 32013 Longarone (BL) - Italy
Executive Officer: Mr. Luigino Boito

and the Client identified in the table “Manufacturer” and/or in the table “Authorized Representative or Legal Representative in the European Union” present in section “Identification data” (hereinafter called “the Applicant”)

INTRODUCTION

The Applicant, intends to entrust DOLOMITICERT Scarl with supervised product checks at random intervals, as provided for Annex VII (Module C 2) of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, for the personal protective equipment described below.

DOLOMITICERT is a Notified Body authorized to perform supervised product checks at random intervals for personal protective equipment according to Annex VII (Module C 2) of the Regulation (EU) 2016/425 of the European Parliament and of the Council. DOLOMITICERT is a body notified by the European Commission, which has assigned it identification code **2008**.

It is hereby agreed as follows:

Art. 1 - INTRODUCTION AND OBJECT OF THE APPLICATION

The preliminary statements must be considered as integral and essential part of this contract. The object of the supervised product checks at random intervals will be the protection device identified in the table “Product – Basic model” and relative “Product – Variants” present in section “Identification data” hereinafter referred to as product.

Art. 2 - REFERENCE LEGISLATION

DOLOMITICERT will submit the product of the Applicant to the procedure of supervised product checks at random intervals, identified in the previous article, on the basis of the applicable harmonized standard, hereinafter referred to as reference law, made up by the Regulation (EU) 2016/425 of the European Parliament and of the Council for personal protection equipment.

Art. 3 - REQUIREMENTS

If DOLOMITICERT is not the notified body that has performed the EU type-examination, the Applicant shall send DOLOMITICERT this Application, the Technical Documentation described in Annex III of the reference law and a copy of the EU type-examination Certificate, in compliance with point 3 of Annex VII of the reference law.

If DOLOMITICERT is not the notified body that has performed the EU type-examination, it may contact the latter in case of difficulties related to the evaluation of the product conformity.

Art. 4 - UNICITY OF THE APPLICATION FOR CHECKS OF THE PRODUCT

According to the dispositions provided for by point 3 of Annex VII of the reference law, the Applicant states that for the product specified in article 1 of this Contract the same Application has not been forwarded to any other notified body.

Art. 5 - CORRESPONDENCE BETWEEN THE PRODUCT OBJECT OF THE EU TYPE-EXAMINATION CERTIFICATE AND THE SAMPLE

The Applicant undertakes to guarantee, with the preparation of suitable procedures, that the production in series continues to be compliant with the sample subjected to the EU type-examination procedure.

Art. 6 - AMOUNTS DUE TO DOLOMITICERT

For the execution of the sampling and tests related to supervised product checks at random interval, the Applicant undertakes to pay DOLOMITICERT the fees stated in the offer prepared by DOLOMITICERT Sales Department in accordance with the current price-list.

Art. 7 – INSPECTIONS PROVIDED BY THE REFERENCE LAW

The Applicant declares to allow access by DOLOMITICERT’s sampling employee, who may be accompanied by personnel from ACCREDIA, the body which accredits DOLOMITICERT’s activities (with the function of observing of the activity of DOLOMITICERT’s sampling employee), and personnel of the relevant Authorities, to the premises selected for the sampling for the purposes of checking production homogeneity, type homogeneity and conformity of the product to the type described in the EU type-examination Certificate, and to the applicable essential health and safety requirements.



Art. 8 – TEST REPORT

At the end of the test procedure for supervised product checks at random intervals, DOLOMITICERT issues a test report to the Applicant, named Annual Confirmation Report of the Certification (ACRC). The Applicant shall make such test report available to national authorities for ten years from the first placing on the market of the PPE.

Art. 9 - APPLICANT'S OBLIGATIONS

- The Applicant undertakes to put all the information necessary to evaluate the product conformity to the applicable essential health and safety requirements at DOLOMITICERT's disposal.
- The Applicant declares to respect the conditions to which the EU type-examination Certificate and Annual Confirmation Report of the Certification (ACRC) was issued.
- Every change in the product, the Technical Documentation or, in the foreseen cases, of the manual or quality control procedures shall be notified to DOLOMITICERT in due time.
- The Applicant declares to respect procedures and regulations provided for by DOLOMITICERT for supervised control checks at random intervals.
- Copies of test reports provided to third parties shall be reproduced in their entirety.

Art. 10 – CE MARKING

During the production process the Applicant affixes, under the responsibility of DOLOMITICERT, the identification number 2008 on each single PPE in compliance with the type described in the EU type-examination Certificate.

Art. 11 - CONFIDENTIALITY

DOLOMITICERT undertakes to consider all the documents and the information (know-how) it has received or that has come to its knowledge regarding the Applicant's organisation and products strictly confidential.

This clause shall remain valid and in force also after the expiry of the contract and until the confidential nature of the information and of the Know-how exchanged during its being in force persists.

All paperwork (documents, letters, communications, etc.) and information relating to certification activities, since the Application for EU type-examination is presented, are considered confidential and access to them is governed by a specific procedure.

The only information that DOLOMITICERT undertakes to communicate to all people requiring them, through specific written application to be sent by fax and/or email to the address which can be found on DOLOMITICERT web site, is the information contained in the issued EU Type-Examination Certificate (without need of any authorization by the Applicant).

DOLOMITICERT's staff at all levels, and external personnel involved in the sampling, tests and issue of the EU Type-Examination Certificate who, while performing their job, may gain knowledge of the information contained in these documents and other information relating to the Applicant DOLOMITICERT has EU Type-Examination agreements with, are all subject to the professional secrecy act.

In the event that the law establishes that certain information should be notified to any Control Authorities requesting it, DOLOMITICERT will inform the Applicant regarding the information which has been disclosed.

Further to instructions from the Applicant, DOLOMITICERT is irrevocably authorized to transmit the records, test reports, EU Type-Examination Certificate and any other information, to any third parties in compliance with current privacy law.

Art. 12 – DOCUMENTS COMPLEMENTARY TO THE CONTRACT

The quotation, submitted by DOLOMITICERT relevant Marketing Department, and approved by the Applicant, and the Regulation for the Certification of Personal Protective Equipment (PQ 16.101.004), available on DOLOMITICERT site (www.dolomitcert.it), are part of this contract.

Art. 13 - JURISDICTION

Any disputes that may arise between the parties that are directly or indirectly related to the application or interpretation of the Regulation for the Certification of Personal Protective Equipment (PQ 16.101.004) and this Application, which cannot be amicably settled between the parties, shall be referred to the exclusive jurisdiction of the Court of Belluno

Date: 15/02/2021

THE APPLICANT
REAL CARE SRL
Via Degli Inventori, 6
41018 SAN CESAREO S/PANARO (MO)
tel 059/912431
Cod. Fisc. e Part. IVA 03934200365
Codice SDI: SUBM70N

DOLOMITICERT S.c.a.r.l.

Lungino Boito

