Certificate of Registration
2020

This is to certify that the registration of

MBM GIYIM DIS TICARET VE SANAYI LIMITED SIRKETI

ORUCREIS MAH. GIYIMKENT 13.SK. GIYIMKENT B140 NO: 22A ESENLER

ISTANBUL, TURKEY- 34235

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by Mbm Giyim Dis Ticaret Ve Sanayi Limited Sirketi

Owner/Operator Number	**10075620**
Date of Registration	**June 21, 2020**
Date of Expiration	**December 31, 2020**
US Agent	**Liberty Management Group Ltd.**
Device Listing Numbers	**See Annex**
Certificate Number	**3006210120**

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

LMG LIBERTY MANAGEMENT GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA

www.fdahelp.us

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: June 21, 2020

Certificate of Registration
2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D409181	FXO	Suit, Surgical - Medical Overall Suit
D409183	OEA	Non-Surgical Isolation Gown - Disposable Gown
D409179	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - Medical Face Mask
D409180	LYU	Accessory, Surgical Apparel - Face shield
D409182	FXP	Cover, Shoe, Operating-Room - Overshoe

CERTIFICATE OPERATIONS
→ Verify Issued Certificate
Application Form

Verify Issued Certificate

Certificate Nr | Company Name (Min First 3 Letters | SEARCH

Please do not request e-mail verification in case you can verify the certificate with scanning QR Codes.
Please compare the information results on the query result on the web page and on the certificate on your side when you make query by QRCode or manual.

The certificate holder, certificate number, certificate type and model name must match.

Query Results

Certificate Holder	MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ.
Certificate Nr	2163-PPE-1368/01
Certificate Type	EN 149:2001+A1:2009 Module C2, Certificate of Conformance
Model Name	MBM / JET FFP2 NR
Valid Through	12 / 03 / 2021
Valid Until	11 / 03 / 2022
Issue Date	12 / 03 / 2021
Status	Valid

For more information please query EU Type Examination Certificate issued to the same manufacturer with

Please register to our newsletter for news and announcements from us, first to be notified.
REGISTER

EU-Konformitätserklärung für eine PSA Kategorie III

Der Hersteller

MBM GIYIM DIS TICARET ve SAN.LTD.STI
Ugur Mumcu Mah. Eski Edirne Asfalti No 564 B Kat 2
Istanbul/Turkey

trägt die Verantwortung für die Ausstellung dieser Konformitätserklärung und erklärt hiermit, dass die nachstehend beschriebene Persönliche Schutzausrüstung (PSA)

Atemschutzmaske, weiß

MBM Model: JET

Atemschutzmaske FFP2 NR ohne Ventil

gemäß den uns vorliegenden relevanten Prüfberichten und/oder Bescheinigungen den Bestimmungen der Verordnung (EU) 2016/425 entspricht: Dabei wurden die folgenden harmonisierten Normen erfüllt:

EN 149:2001+A1:2009

Die notifizierte Stelle:

Universal Uygunluk Degerlendirme Hizmetleri ve Tic. A.S.
Necip Fazil Bulvari Keyap Sitesi E2 Blok No: 44/84 Yukari Dudullu
Ümranie-Istanbul
Turkey

Kennnummer 2163

hat die EU-Baumusterprüfung durchgeführt und die EU Baumusterprüfbescheinigung

(Zertifikat-Nr. 2163-PPE-1368)

ausgestellt. Die PSA unterliegt folgendem Konformitätsbewertungsverfahren:
Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess. Durchgeführt durch:

Universal Uygunluk Degerlendirme Hizmetleri ve Tic. A.S., Kennnummer 2163

Unterzeichnet für und im Namen von MBM GIYIM DIS TICARET ve SAN.LTD.STI

Istanbul, 04.01.2020

Ergün Kök
CEO
MBM GIYIM DIS TICARET
ve SAN.LTD.STI

MBM GİYİM
DIŞ TİC. VE SAN.LTD.ŞTİ
Uğur Mumcu Mh. Eski Edirne Asfaltı No:564 B Kat:2
Sultangazi/İSTANBUL Tel: 0212 476 38 88
Alışalan V.D.: 613 074 4416

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CONFORMITY TO TYPE CERTIFICATE

Certificate No: 2163-PPE-1368/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ.
Uğur Mumcu Mah. Eski Edirne Asfaltı No:564/B Kat:4 Sultangazi - İstanbul /TURKEY

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
MBM / JET	FFP2 NR	2163-PPE-1368	28.08.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **12/03/2021** and will be valid for one year, until **11/03/2022** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSAL
CERTIFICATION

UNIVERSAL CERTIFICATION CONFORMITY ASSESSMENT CO.
Tatlisu Mah. Arif Ay Sk. No:16/3 Umraniye, Istanbul / TURKEY

PARTIAL TEST REPORT

Report Date:02.03.2021
Report Number:03-2021-T0709

CLIENT and SAMPLE INFORMATION

TEST OWNER	MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ.		
ADDRESS	Uğur Mumcu Mah. Eski Edirne Asfaltı No:564/B Kat:4 Sultangazi İstanbul TURKEY		
SAMPLE DESCRIPTION	Folding type protective mask- C2Samples		
BRAND NAME – MODEL	MBM – JET FFP2 NR		
TESTING STANDARD	EN 149:2001+A1:2009		
CASE NUMBER	CE-PPE-3380		
SAMPLE RECEIVE DATE	12.02.2021	TESTING START DATE	12.02.2021
DISINFECTION INSTRUCTION *If applicable*	Not given, single use only		
NUMBER OF SAMPLES	15	SAMPLE IDs:	1 – 15
AS RECEIVED SAMPLE NO	1-15		
	Flow cond.	10-11-12(As Received)	

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*	*EVALUATION*
EN 149:2001 + A1:2009 clause 8.11 EN 13274-7:2019	Penetration of Filter Material	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Breathing Inhalation Resistance-30 l/min	**Pass**	**See results**
	Breathing Inhalation Resistance-95 l/min	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Exhalation Resistance, flow rate 160 l/min	**Pass**	**See results**

TEST RESULTS and EVALUATION

7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

REQUIREMENT	RESULTS	COMMENT
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Pass	The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use

Lab A

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at (37 ± 2) °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ±1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

REQUIREMENT	RESULTS	COMMENT
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Pass	The materials used were able to withstand handling and wear during the limited laboratory testing carried out.
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass	It was not constitute a hazard or nuisance for the wearer.
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Pass	None of the specimens conditioned suffered mechanical failure.
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass	None of the specimens had not collapse after conditioning.

Lab B

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

REQUIREMENT	RESULTS	COMMENT
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	N/A	This article is not applicable for tested protective mask which is single use disposable mask.

7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs while visual inspection and performance tests.

Lab A

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

7.9.2 PENETRATION OF FILTER MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

Test Method: Described in Clause 8.11

REQUIREMENT	RESULTS	COMMENT
<table><tr><td rowspan="2">Classification</td><td colspan="2">Max penetration of test aerosol</td></tr><tr><td>NaCl test 95 l/min %max</td><td>Paraffin oil test 95 l/min %max</td></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>	Pass	Detail refer to Annex IIIA and IIIB

Annex IIIA-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Sodium Chloride in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
22	As received	0,39	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second and third protection class (FFP1, FFP2,FFP3)
23		0,32		
24		0,30		

Annex IIIB-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
25	As received	1,65	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and second protection class (FFP1, FFP2)
26		1,01		
27		1,10		

Lab A + B

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

Test Method: Described in Clause 8.9

REQUIREMENT	RESULTS	COMMENT
See table below	Pass	Classified as FFP2 Detail refer to Annex VIA-VIB

Classification	Max permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Annex VIA-Test Result:
The test results obtained are given in the tables as follows;

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		Flow rate 30 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
28	As received	0,56	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,66	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed Qualifies FFP1,FFP2,FFP3
29		0,55		1,60		
30		0,56		1,65		

Exhalation Resistance

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
28	As received	160l/min	2,13	2,17	2,10	2,15	2,16	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed Qualifies FFP1,FFP2, FFP3
29			2,08	2,12	2,04	2,04	2,09		
30			2,17	2,22	2,15	2,15	2,17		

Lab A

Pass	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

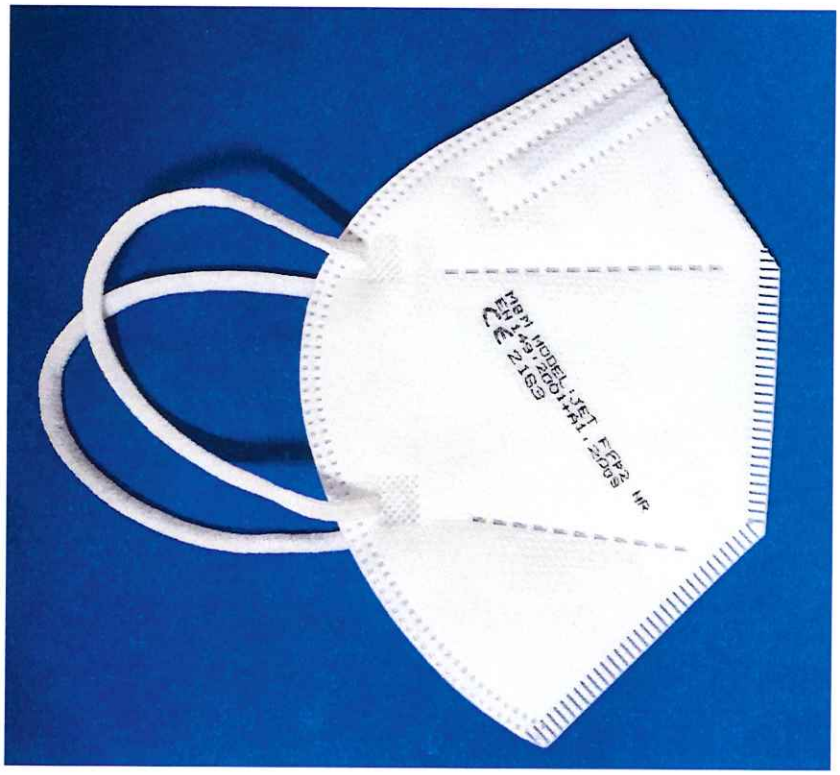
UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş Tatlısu Mh. Arif Ay Sk. No:16 Ümraniye / İSTANBUL T:+90 216 455 80 80 F: +90 216 455 80 08 info@universalcert.com

LABORATORY INFORMATION

Code	Laboratory Name	Competency Explanations
Lab A	UNIVERSAL SERTIFIKASYON VE GOZETIM HIZMETLERI TIC. LTD. STI.	Internal Laboratory Services of Notified Body
Lab B	GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI	Report Number: GTL-MC-061

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

Sample Photo



- End of Report –

TEST REVIEW

MURAT AYDEMİR

APPROVAL

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mah. Arif Ay Sk. No:16/3 Ümraniye / İSTANBUL
Alemdağ V.D.: 892 061 8452
Mersis No: 0892061845200001

OSMAN CAMCI
Director

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EG BAUMUSTERPRÜFBESCHEINIGUNG

EU Type Examination Certificate

Zertifikat Nr: 2163-PPE-1368

Atemschutzgeräte, die Halbmasken zum Schutz vor Partikeln zu Filtern, werden von der

Mbm Giyim Diş Ticaret ve San. Ltd. Şti.

Uğur Mumcu Mah. Eski Edirne Asfaltı No:564/B Kat:4 Sultangazi İstanbul TÜRKEI

hergestellt
Diese Produkte werden gemäß

EN 149: 2001 + A1: 2009 Atemschutzgeräte getestet und bewertet – die Filterung von Halbmasken zum Schutz vor Partikeln - Anforderungen, Prüfung, Kennzeichnung

Die Prüfungen und Bewertungen basieren auf der Typprüfung, die mit der Bewertung von Prüfberichten durchgeführt wurde, technische Akte gemäß Anhang 5 der Verordnung über persönliche Schutzausrüstung (EU) 2016/425. Es wird genehmigt, dass das Produkt die Anforderungen der Verordnung erfüllt.

Produkt Bestimmung

Markenname: MBM **Modell:** JET
Halbmaske filtern
Klassifizierung: FFP2 NR

Hier darf der Hersteller die notifizierte Körpernummer (2163) verwenden und das CE-Zeichen, wie unten gezeigt, auf den oben angegebenen Produktmodellen der Kategorie III mit anbringen;

- Ausstellung einer entsprechenden EU-Konformitätserklärung gemäß **Anhang 9 der Verordnung über persönliche Schutzausrüstung (EU) 2016/425.**
- Laufende erfolgreiche Erfüllung der Anforderungen der Verordnung **über persönliche Schutzausrüstung (EU) 2016/425 und der harmonisierten Normen, die durch Bewertungen auf der Grundlage von Anhang 7 (Modul C2) oder Anhang 8 (Modul D)** der Verordnung bis spätestens sichergestellt werden 1 Jahr ab Beginn der Serienproduktion

Dieses Zertifikat wird ursprünglich **am 28.08.2020** ausgestellt und ist 5 Jahre lang gültig, wenn sich die einschlägige harmonisierte Norm nicht ändert, was sich auf die grundlegenden Gesundheits- und Sicherheitsanforderungen auswirkt.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

APPLICANT NAME:	MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ.
APPLICANT ADDRESS:	Uğur Mumcu Mah. Eski Edirne Asfaltı No:564/B Kat:4 Sultangazi/İSTANBUL
MANUFACTURER NAME: *Full legal entity name*	MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ.
MANUFACTURER ADDRESS: *NOT a Post Office address*	Uğur Mumcu Mah. Eski Edirne Asfaltı No:564/B Kat:4 Sultangazi/İSTANBUL
PRODUCT TYPE: *E.g. industrial helmet*	Filtering half mask
APPLICABLE STANDARDS: *EN standards & publication date*	EN 149:2001+A1:2009
MODEL IDENTIFICATION: *As per marking & EU Declaration of Conformity*	MBM - JET
PERFORMANCE CLASSIFICATION: *If applicable, e.g. FFP1 NR*	FFP2 NR
TECHNICAL FILE REFERENCE: *Apply your own ID reference*	TD-01
DATE AND REVISION CONTROL: *e.g. 11 May 2019, Issue 1. SEE ALSO SECTION 17*	15.07.2020 (rev 0)

PRODUCT IMAGE

15.07.2020

TABLE OF CONTENTS

1. AUTHORISED REPRESENTATIVE *This section is only applicable if an EU authorised representative has been appointed by a manufacturer*	
Authorised representative appointed?	NO
Company Name:	
Full Postal Address:	
DECLARATION	
NAME: Click or tap here to enter text.	**DATE:** Click or tap to enter a date.
MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☐	

2. INTENDED USE OF THE PPE *This should be a brief description of the product, its use, and the risks against which it is intended to protect.*
The PPE model identified on page 1 and the subject of this technical file is intended to be used as a single shift use particle filtering half masks for protection against solid and liquid aerosols.

3. TECHNICAL SPECIFICATION OR HARMONISED STANDARDS *This section is split into two parts. (3.1) should be completed if a technical specification has been used, and (3.2) should be completed if harmonised standards have been used.*	
3.1 TECHNICAL SPECIFICATION *A technical specification is used typically where there is no appropriate harmonised standard, or there is a gap in harmonised standards requiring a technical specification to be produced. A technical specification can incorporate some clauses of harmonised standards. Where a technical specification has been used, please complete the below.*	
Technical specification used?	NO
Harmonised standard(s) clauses used?	NO
STANDARD NUMBER & DATE OF PUBLICATION	**CLAUSE NUMBERS USED**

3.2. HARMONISED STANDARDS

Please list all of the harmonised standards applicable to the product to test conformity to the EHSRs and confirm if the standard has been used in full. If only some clauses of a standard have been applied, those clauses should be listed.

STANDARD & DATE	**FULL OR PART USED**	**CLAUSE NUMBERS USED**
EN 149:2001+A1:2009	Has been used in full? YES	Full test

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
1	**GENERAL REQUIREMENTS APPLICABLE TO ALL PPE**					
	PPE must provide adequate protection against the risks against which it is intended to protect.	YES	EN 149:2001+A1:2009			
1.1	**Design principles**					
1.1.1	***Ergonomics***					
	PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.	YES	EN 149:2001+A1:2009 5 / 7.7 / 7.9			
1.1.2	***Levels and classes of protection***					
1.1.2.1	***Optimum level of protection***					
	The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.	YES	EN 149:2001+A1:2009 5 / 7.7 / 7.9 / 7.12			
1.1.2.2	***Classes of protection appropriate to different levels of risk***					
	Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.	YES	EN 149:2001+A1:2009 7.9			
1.2	**Innocuousness of PPE**					
1.2.1	***Absence of inherent risks and other nuisance factors***					
	PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.	YES	EN 149:2001+A1:2009 7.12 / 7.14 / 7.16			
1.2.1.1	***Suitable constituent materials***					
	The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.	YES	EN 149:2001+A1:2009 7.5 / 7.7 / 7.10 / 7.11			
1.2.1.2	***Satisfactory surface condition of all PPE parts in contact with the user***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.	YES	EN 149:2001+A1:2009 7.7 / 7.8			
1.2.1.3	***Maximum permissible user impediment***					
	Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.	YES	EN 149:2001+A1:2009 7.7 / 7.14			
1.3	**Comfort and effectiveness**					
1.3.1	***Adaptation of PPE to user morphology***					
	PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.	YES	EN 149:2001+A1:2009 7.7			
1.3.2	***Lightness and strength***					
	PPE must be as light as possible without prejudicing its strength and effectiveness.	YES	EN 149:2001+A1:2009 7.4 / 7.5 / 7.7			
	PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.	YES	EN 149:2001+A1:2009 7.4 / 7.5 / 7.7			
1.3.3	***Compatibility of different types of PPE intended for simultaneous use***					
	If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	NO				
1.3.4	***Protective clothing containing removable protectors***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.	NO				
1.4	**Manufacturer's instructions and information**					
	In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:	YES	EN 149:2001+A1:2009 10	X		
	(a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;	YES	EN 149:2001+A1:2009 10	X		
	(b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;	YES	EN 149:2001+A1:2009 10	X		
	(c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;	NO				
	(d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;	YES	EN 149:2001+A1:2009 10	X		
	(e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;	YES	EN 149:2001+A1:2009 10	X		
	(f) where applicable, the type of packaging suitable for transport;	YES		X		
	(g) the significance of any markings (see point 2.12);	YES	EN 149:2001+A1:2009 10	X		
	(h) the risk against which the PPE is designed to protect;	YES		X		
	(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;	YES		X		
	(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;	YES	EN 149:2001+A1:2009 10	X		
	(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;	YES			X	

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	(l) the internet address where the EU declaration of conformity can be accessed.	YES				
	The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.	YES				
2	**ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE**					
2.1	**PPE incorporating adjustment systems**					
	If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.	NO				
2.2	**PPE enclosing the parts of the body to be protected**					
	PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.	NO				
2.3	**PPE for the face, eyes and respiratory system**					
	Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.	YES	EN 149:2001+A1:2009 7.14	X		
	The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.	NO				
	If necessary, such PPE must be treated or provided with means to prevent misting-up.	NO				
	Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	NO				
2.4	**PPE subject to ageing**					
	If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.	YES	EN 149:2001+A1:2009 9 / 10	X	X	

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, **his instructions** must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.	YES	EN 149:2001+A1:2009 9 / 10	X	X	
	Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be NBted or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.	NO				
2.5	**PPE which may be caught up during use**					
	Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.	NO				
2.6	**PPE for use in potentially explosive atmospheres**					
	PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.	NO				
2.7	**PPE intended for rapid intervention or to be put on or removed rapidly**					
	Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.	NO				
	Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.	NO				
2.8	**PPE for intervention in very dangerous situations**					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.	YES	EN149:2001 10	X		
	The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.	YES	EN149:2001 10	X		
	Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.	NO				
2.9	**PPE incorporating components which can be adjusted or removed by the user**					
	Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.	NO				
2.10	**PPE for connection to complementary equipment external to the PPE**					
	Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.	NO				
2.11	**PPE incorporating a fluid circulation system**					
	Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.	NO				
2.12	**PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety**					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.	YES	EN149:2001 9		X	
	Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.	NO				
2.13	**PPE capable of signalling the users presence visually**					
	PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.	NO				
2.14	**Multi-risk PPE**					
	PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	NO				
3	**ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS**					
3.1	**Protection against mechanical impact**					
3.1.1	***Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.	NO				
3.1.2	***Falls***					
3.1.2.1	***Prevention of falls due to slipping***					
	The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.	NO				
3.1.2.2	***Prevention of falls from a height***					
	PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.	NO				
	Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.	NO				
	The manufacturer's instructions must specify, in particular, all relevant information relating to:	NO				
	(a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;	NO				
	(b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.	NO				
3.1.3	***Mechanical vibration***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.	NO				
3.2	**Protection against static compression of a part of the body**					
	PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.	NO				
3.3	**Protection against mechanical injuries**					
	PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.	NO				
3.4	**Protection in liquids**					
3.4.1	***Prevention of drowning***					
	PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.	NO				
	PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.	NO				
	Under the foreseeable conditions of use:	NO				
	(a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;	NO				
	(b) inflatable PPE must be capable of inflating rapidly and fully.	NO				
	Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	(a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;	NO				
	(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;	NO				
	(c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.	NO				
3.4.2	***Buoyancy aids***					
	Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.	NO				
3.5	**Protection against the harmful effects of noise**					
	PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council (1).	NO				
	Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.	NO				
3.6	**Protection against heat and/or fire**					
	PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.	NO				
3.6.1	***PPE constituent materials and other components***					
	Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.	NO				
	Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.	NO				
	PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).	NO				
	PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.	NO				
3.6.2	***Complete PPE ready for use***					
	Under the foreseeable conditions of use:	NO				
	(a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;	NO				
	(b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.	NO				
	If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.	NO				
	If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.	NO				
3.7	**Protection against cold**					
	PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.	NO				
3.7.1	***PPE constituent materials and other components***					
	Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.	NO				
	PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).	NO				
3.7.2	***Complete PPE ready for use***					
	Under the foreseeable conditions of use, the following requirements apply:	NO				
	(a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;	NO				
	(b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.	NO				
	If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.	NO				
3.8	**Protection against electric shock**					
3.8.1	***Insulating equipment***					
	PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.	NO				
	To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.	NO				
	Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or NBtions to be conducted.	NO				
	The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.	NO				
3.8.2	***Conductive equipment***					
	Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
3.9	**Radiation protection**					
3.9.1	***Non-ionising radiation***					
	PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.	NO				
	To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.	NO				
	Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.	NO				
	Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.	NO				
	The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.	NO				
3.9.2	***Ionising radiation***					
3.9.2.1	***Protection against external radioactive contamination***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.	NO				
	Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.	NO				
	Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.	NO				
3.9.2.2	***Protection against external irradiation***					
	PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.	NO				
	The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).	NO				
	PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.	NO				
3.10	**Protection against substances and mixtures which are hazardous to health and against harmful biological agents**					
3.10.1	***Respiratory protection***					
	PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
3.10.2	***Protection against cutaneous and ocular contact***					
	PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.	NO				
	To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	NO				
3.11	**Diving equipment**					
	The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.	NO				
	Where the foreseeable conditions of use so require, the diving equipment must comprise the following:	NO				
	(a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);	NO				
	(b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);	NO				
	(c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).	NO				

5. RISK ASSESSMENT

The risk assessment should identify any other risks not already covered by the EHSRs, based on the intended use of the product. Please include a risk assessment statement. If there are no additional risks the statement should confirm this. If there are additional risks, please describe the risk; the action taken may be either testing/user info or marking and you need only mark this with an 'X'. If the action is 'other' please briefly describe the action taken.

MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ. have undertaken a risk assessment of our product(s) considering the intended use, and the possibility of mis-use. Our product is Protective Mask and intended to product against particle and dust and we have not identified any additional risks, not already addressed by the Essential Health & Safety Requirements of the PPE Regulation.

SPECIFIC RISKS	**ACTIONS TAKEN TO ADDRESS (Mark with X)**			
Description of risk	**TEST**	**USER INFO**	**MARKING**	**OTHER (DESCRIBE)**
N/A				

6. DESIGN AND MANUFACTURING DRAWINGS

The design and manufacturing drawings should be detailed, including all component and sub-components, and also provide dimensions for each. Electrical elements should be clearly detailed down to circuit level. If components are bought in for assembly purposes and not manufactured, a technical sheet or similar document from the supplier will be sufficient.

INSERT DRAWINGS AS AN IMAGE, OR LIST THE TITLE AND ISSUE/REVISION STATUS HERE & ATTACH DOCUMENTS

NOTE: The drawings should be detailed and include dimensions down to sub-component level.

Refer to the attachment.

7. COMPONENT AND MATERIALS

*Please list down your components and subcomponents and detail the materials, **and grades** of materials. If components and materials are purchased from a supplier, the supplier's unique reference for the material will be acceptable.*

COMPONENT OR SUB COMPONENT	MATERİAL	GRADE	ALREADY CERTIFIED? INSERT CERT NO	EXTERNALLY SOURCED
1.OUTSİDE LAYER	NON WOVEN	60 Gr		MOĞUL FABRIC
2.LAYER	NON WOVEN	40 Gr		MOĞUL FABRIC
3.FİLTERİNG LAYER	MELT-BLOWN	25 Gr		HAS GROUP MEDICAL
4.FİLTERİNG LAYER	MELT-BLOWN	25 Gr		HAS GROUP MEDICAL
5. INNER LAYER	NON WOVEN	30 Gr		MOĞUL FABRIC

MATERIAL DECLARATION

The material and parts named above, including any of their possible decomposition products, are not known to cause adverse effects to user hygiene or health, nor are likely to cause irritation, during normal use.

NAME	DATE:15/07/2020

MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☒

7.1 PRODUCT TO BE FITTED TO ANOTHER MANUFACTURER'S PRODUCT

This section is applicable if your product is designed to be used with another manufacturer's product, e.g. a helmet-mounted earmuff. In this case, you will need to provide evidence that you have an agreement with the applicable manufacturer(s) to use their product during testing, and that they will advise of any design changes to their products, or any issues with production, e.g. product recalls.

Attachments listed below should be sent with the completed technical file

Does your product rely on another manufacturers product to be used as a complete PPE?	NO	
MANUFACTURER NAME	**DOCUMENT TITLE & ISSUE/REVISION STATUS**	**ATTACHED?**

7.2 SPARE PARTS & ACCESSORIES

This section is applicable if you supply spare and accessories for the certified product. Please list the part and confirm the type, and where the spare part of accessory is listed. If spare parts and accessories are listed on a separate sheet to the user information, the sheet should be supplied with the technical file.

Does your product have spare parts or accessories available?	NO	
DESCRIPTION	**TYPE?**	**DETAILED IN?**

8. USER INFORMATION DOCUMENT

Please either insert a copy of your user manual/information or attach a copy
Attachments listed below should be sent with the completed technical file

INSERT USER INFORMATION DOCUMENT TEXT OR ATTACH DOCUMENTS
Refer to the attachment.

8.1 DECLARATION – MATERIALS FOR MAINTENANCE, CLEANING AND DISINFECTING

We declare that the products/materials recommended for maintenance, cleaning and disinfecting do not have any adverse effect on the PPE or the user when applied in accordance with the relevant instructions.

MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☐

8.2 DECLARATION – SUPPLY OF USER INFORMATION

We declare that the user information accompanies each smallest commercially available unit.

MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☒

9. PRODUCT MARKING

Please either insert a copy of your product marking artwork or attach a copy
Attachments listed below should be sent with the completed technical file

INSERT USER PRODUCT MARKING ARTWORK OR ATTACH DOCUMENTS
We will follow the marking artwork to moulded on the helmet.
The postal address could be found in user information

MBM GİYİM DIŞ TİCARET VE SAN. LTD. ŞTİ CE 2163
MBM – JET FFP2 NR
Uğur Mumcu Mah. Eski Edirne Asfaltı No:564/B Kat:4 Sultangazi/İSTANBUL

9.1 PACKAGING MARKING

Please either insert a copy of your packaging marking artwork or attach a copy
Attachments listed below should be sent with the completed technical file

INSERT USER PACKAGING MARKING ARTWORK OR ATTACH DOCUMENTS
Refer to the attachment.

10. EU DECLARATION OF CONFORMITY

Please provide a draft or example of your EU Declaration of conformity so we can check the content for you.
Attachments listed below should be sent with the completed technical file

INSERT EXAMPLE DECLARATION OF CONFORMITY OR ATTACH DOCUMENTS
The EU DoC is to be delivered with accompanies the user information and masks together.