Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 03 din 08.09.2023

Solicitantul **„MedGlobalFarm" SRL**, cu sediul **R.Moldova, mun.Chisinau, str.Miron Costin 17/7, of.71**, tel./fax: 022-523090, e-mail medglobalfarm@mail.ru, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	A-267V	Respiratoar cu valva respiratory FFP2	FFP2 NR D With Exhalation Valve	FFP2 NR D With Exhalation Valve	47783

Se anexează următoarele acte:

declaraţia de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
certificatul de conformitate CE valabil pentru dispozitivele fabricate;
actul prin care producătorul îşi desemnează reprezentantul/

Data 08.09.2023 Semnătura _____

Tabelul de recepţionare a notificării
(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Granaci Boris
Date: 2023.09.13 15:13:53 EEST
Reason: MoldSign Signature
Location: Moldova

(FR) DÉCLARATION UE DE CONFORMITÉ
(EN) EU DECLARATION OF CONFORMITY
(NL) EU-CONFORMITEITSVERKLARING
(DE) EU-KONFORMITÄTSERKLÄRUNG
(ES) DECLARACIÓN UE DE CONFORMIDAD
(IT) DICHIARAZIONE DI CONFORMITÀ UE
(PL) DEKLARACJA ZGODNOŚCI UE
(RO) DECLARAȚIA DE CONFORMITATE UE

1. EPI PPE PBM PSA EPI DPI ŚOI EIP	A-167, A-167V, A-167V-E, A- 267, A-267V, A-367, A-367V, Z-167, Z-167V, Z-267, Z-267V, C-067, C-067V, C-167, C- 167V, C-267, C-267V, C-267- AC, C-267V-AC, C-367V, F- 167, F-167V, F-267, F-267V, F-267-AC, F-267V-AC, P-167, P-167V, P-167-AC, P-167V-AC, P-167V-E, P-167V-AC-E, P-267, P-267V, P-267-AC, P- 267V-AC, P-267V-E, P-267V- AC-E, P-367, P-367V, P-367V-E, P-367V-AC – P-367-S, P-367V-S, P-367V-AC-S, S-167, S-167V, S-267, S-267V, S-267- AC, S-267V-AC, S-367V, S- 367V-AC, SR-267V, SR-267V- AC

2. Nom et adresse du fabricant Name and address of the manufacturer Naam en adres van de fabrikant Name und Anschrift des Herstellers Nombre y dirección del fabricante Nome e indirizzo del fabbricante Nazwa i adres producenta Denumirea și adresa producătorului	M.F.A. İŞ GÜVENLİĞİ MEDİKAL TEKSTİL İMALAT TİCARET SANAYİ LTD. ŞTİ. Elvanpazarcık Beldesi, Hayat Mahallesi, Baruthane Cad., No:21/1, 67100, Merkez, Zonguldak, Türkiye

3.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant
This declaration of conformity is issued under the sole responsibility of the manufacturer
Deze conformiteitsverklaring wordt op eigen verantwoording van de fabrikant verstrekt
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante
La presente dichiarazione di conformità è rilasciata sotto l'esclusiva responsabilità del fabbricante
Niniejszą deklarację zgodności wydaje się na wyłączną odpowiedzialność producenta
Prezenta declarație de conformitate este eliberată pe răspunderea exclusivă a producătorului

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IDNO 1016600000765
REPUBLICA MOLDOVA, mun. CHIȘINĂU

4. Objet de la declaration Object of the declaration Voorwerp van de verklaring Gegenstand der Erklärung Objeto de la declaración Oggetto della dichiarazione Przedmiot deklaracji Obiectul declarației	Masque / Mask / Masker / Masken / Mascarilla / Maschera / Maskować / Masca MFA

5.
L'objet de la déclaration décrit au point 4 est conforme à la législation d'harmonisation de l'Union applicable:
The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:
Het in punt 4 beschreven voorwerp is conform met de desbetreffende harmonisatiewetgeving van de Unie:
Der unter Nummer 4 beschriebene Gegenstand der Erklärung entspricht den einschlägigen Harmonisierungsrechtsvorschriften der Union:
El objeto de la declaración descrito en el punto 4 anterior es conforme con la legislación de armonización de la Unión applicable:
L'oggetto della dichiarazione di cui al punto 4 è conforme alla pertinente normativa di armonizzazione dell'Unione:
Opisany w pkt 4 przedmiot niniejszej deklaracji jest zgodny z odpowiednimi wymaganiami unijnego prawodawstwa harmonizacyjnego:
Obiectul declarației descris la punctul 4 este în conformitate cu legislația armonizată relevantă a Uniunii:

RÈGLEMENT / REGULATION / VERORDENING / VERORDNUNG / REGLAMENTO / REGOLAMENTO / ROZPORZĄDZENIE / REGULAMENTUL (EU) 2016/425

6. Références des normes harmonisées pertinentes appliquées ou des autres spécifications techniques par rapport auxquelles la conformité est déclarée: References to the relevant harmonised standards used, or references to the other technical specifications, in relation to which conformity is declared: Vermelding van de relevante toegepaste geharmoniseerde normen, met inbegrip van de datum van de norm, of van de andere technische specificaties, met inbegrip van de datum van de specificatie, waarop de conformiteitsverklaring betrekking heft: Angabe der verwendeten einschlägigen harmonisierten Normen oder sonstigen technischen Spezifikationen, für die die Konformität erklärt wird, einschließlich des Datums der Normen bzw. sonstigen technischen Spezifikationen: Referencias a las normas armonizadas aplicables utilizadas, incluidas sus fechas, o	EN149:2001 +A1:2009

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
«MEDGLOBALFARM»
IDNO 1016600000765
REPUBLICA MOLDOVA, mun. CHIȘINĂU

referencias a las otras especificaciones técnicas, incluidas sus fechas, respecto a las cuales se declara la conformidad: Riferimenti alle pertinenti norme armonizzate utilizzate, compresa la data della norma, o alle altre specifiche tecniche, compresa la data della specifica, in relazione alle quali è dichiarata la conformità: Odniesienia do właściwych norm zharmonizowanych, które zastosowano, wraz z datą normy, lub do innych specyfikacji technicznych, wraz z datą specyfikacji, w odniesieniu do których deklarowana jest zgodność Trimiteri la standardele armonizate relevante folosite, inclusiv data standardului, sau trimiteri la celelalte specificații tehnice, inclusiv data specificației, în legătură cu care se declară conformitatea	

7.
L'organisme notifié / The notified body / De aangemelde instantie / Die notifizierte Stelle / El organismo notificado / L'organismo notificato / Jednostka notyfikowana / Organismul notificat **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797.**

A effectué l'examen UE de type (module B) / Performed the EU type-examination (Module B) / Heeft het EU- typeonderzoek (module B) verricht / Hat die EU-Baumusterprüfung (Modul B) / Ha efectuado el examen UE de tipo (módulo B) / Ha svolto l'esame UE del tipo (modulo B) r/zeprowadziła badanie typu UE (moduł B) / a efectuat examinarea UE de tip (modulul B) et a établi l'attestation d'examen UE de type **CE 688360** / and issued the EU type-examination certificate **CE 688360** e/n het certificaat van EU-typeonderzoek **CE 688360** / udrchgeführt und die EU- Baumusterprüfbescheinigung **CE 688360** / y ha expedido el certificado de examen UE de tipo **CE 688360** / e ha rilasciato il certificato di esame UE del tipo **CE 688360** / i wydała certyfikat badania typu UE **CE 688360** / și a eliberat certificatul de examinare UE de tip **CE 688360**

8.
L'EPI est soumis à la procédure d'évaluation de la conformité: conformité au type sur la base de l'assurance de la qualité du mode de production (module D) sous la surveillance de l'organisme notifié **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797.(Catégorie III)**

The PPE is subject to the conformity assessment procedure: conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (Category III)**

Het persoonlijk beschermingsmiddel is onderworpen aan de conformiteitsbeoordelingsprocedure Conformiteit met het type op basis van kwaliteitsborging van het productieproces (module D) onder toezicht van de aangemelde instantie BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (Categorie III)

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 MOLDOVA, mun. CHIŞINĂU

Die PSA unterliegt folgendem Konformitätsbewertungsverfahren Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess (Modul D) unter Überwachung der notifizierten Stelle **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (Kategorie III)**

El EPI está sujeto al procedimiento de evaluación de la conformidad: conformidad con el tipo basada en el aseguramiento de la calidad del proceso de producción (módulo D) bajo la supervisión del organismo notificado **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (Categoría III)**

Il DPI è oggetto della procedura di valutazione della conformità: conformità al tipo basata sulla garanzia di qualità del processo di produzione (modulo D) sotto la sorveglianza dell'organismo notificato **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (Categoria III)**

W stosownych przypadkach ŚOI podlegają procedurze oceny zgodności albo zgodności z typem w oparciu o zapewnienie jakości procesu produkcji (moduł D) pod nadzorem jednostki notyfikującej **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (kategoria III)**

După caz, EIP face obiectul procedurii de evaluare a conformității: conformitatea de tip bazată pe asigurarea calității procesului de producție (modulul D) sub supravegherea organismului notificat **BSI Group The Netherlands B.V. John M. Keynesplein 9, 1066 EP, Amsterdam, The Nerherlands, Notified Body Number is 2797. (Categoria III)**

Fatih FURTUN
General Manager

Signé par et au nom de:
Signed for and on behalf of:
Ondertekend voor en namens:
Unterzeichnet für und im Namen von:
Firmado por y en nombre de:
Firmato a nome e per conto di:
Podpisano w imieniu:
Semnat pentru și în numele:

Zonguldak, TÜRKİYE, 25.01.2020

Date et lieu d'établissement:
Place and date of issue:
Plaats en datum van afgifte:
Ort und Datum der Ausstellung:
Lugar y fecha de expedición:
Luogo e data del rilascio:
Miejsce i data wydania:
Locul și data eliberării:

M.F.A. İŞ GÜVENLİĞİ MEDİKAL TEKSTİL İMALAT TİCARET SANAYİ LİMİTED ŞİRKETİ

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA, mun. CHIȘINĂU

bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

MFA Is Guvenligi Medikal A.S.
Elvanpazarcik Beldesi Hayat Mah. Baruthane Cad. No:21/1
Merkez
Zonguldak
67990
Turkey

Holds Certificate Number: CE 758378

In respect of:

Filtering masks to EN 149:2001+A1:2009
Various models, see continuation sheet for details.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 758378

Product Specification

Vertical Fold Flat Range with clogging

Description:	**A- Series - Vertical fold flat disposable face mask with clogging option 7.17**
Technical specification:	**EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles. Classification –Single shift NR
FFP Class:	**FFP1 NR D**
Models:	A-167
	A-167V (mask with exhalation valve fitted)
	A-167V-E (mask with exhalation valve fitted)
FFP Class:	**FFP2 NR D**
Models:	A-267
	A-267V (mask with exhalation valve fitted)
FFP Class:	**FFP3 NR D**
Models:	A-367
	A-367V (mask with exhalation valve fitted)

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Product Specification (continued)

Description:	**C- Series - Vertical fold flat disposable face mask with clogging option 7.17**	
Technical specification:	**EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles. Classification – Single shift NR	
FFP Class:	**FFP1 NR D**	
Models:	C-067	
	C-067V	(mask with exhalation valve fitted)
	C-167	
	C-167V	(mask with exhalation valve fitted)
FFP Class:	**FFP2 NR D**	
Models:	C-267	
	C-267V	(mask with exhalation valve fitted)
	C-267-AC	(mask with activated charcoal)
	C-267V-AC	(mask with activated charcoal and exhalation valve fitted)
FFP Class:	**FFP3 NR D**	
Model:	C-367V	(mask with exhalation valve fitted)

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Product Specification (Continued)

Description:	**F - Series – Conical Type disposable face mask with clogging option 7.17**
Technical specification:	**EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles. Classification – Single shift NR
FFP Class:	**FFP1 NR D**
Models:	F-167
	F-167V (mask with exhalation valve fitted)
FFP Class:	**FFP2 NR D**
Models:	F-267
	F-267V (mask with exhalation valve fitted)
	F-267-AC (mask with activated charcoal)
	F-267V-AC (mask with activated charcoal and exhalation valve fitted)

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Product Specification (Continued)

Description:	**P - Series - Vertical fold flat disposable face mask with clogging option 7.17**	
Technical specification:	**EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles. Classification – Single shift NR	
FFP Class:	**FFP1 NR D**	
Models:	P-167	
	P-167V	(mask with exhalation valve fitted)
	P-167-AC	(mask with activated charcoal)
	P-167V-AC	(mask with activated charcoal and exhalation valve fitted)
	P-167V-E	(mask with exhalation valve fitted)
	P-167V-AC-E	(mask with activated charcoal and exhalation valve fitted)
FFP Class:	**FFP2 NR D**	
Models:	P-267	
	P-267V	(mask with exhalation valve fitted)
	P-267-AC	(mask with activated charcoal)
	P-267V-AC	(mask with activated charcoal and exhalation valve fitted)
	P-267V-E	(mask with exhalation valve fitted)
	P-267V-AC-E	(mask with activated charcoal and exhalation valve fitted)
FFP Class:	**FFP3 NR D**	
Models:	P-367	
	P-367-S	(mask is smaller in size than the original model P-367)
	P-367V	(mask with exhalation valve fitted)
	P-367V-S	(mask is smaller in size than the original model P-367V)
	P-367V-E	(mask with exhalation valve fitted)
	P-367V-AC	(mask with activated charcoal and exhalation valve fitted)
	P-367V-AC-S	(mask is smaller in size than the original model P-367V-AC)

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Product Specification (Continued)

Description:	**S - Series – Conical type disposable face mask with clogging option 7.17**
Technical specification:	**EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles. Classification – Single shift NR

FFP Class:	**FFP1 NR D**	
Models:	S-167	
	S-167V	(mask with exhalation valve fitted)

FFP Class:	**FFP2 NR D**	
Models:	S-267	
	S-267V	(mask with exhalation valve fitted)
	S-267-AC	(mask with activated charcoal)
	S-267V-AC	(mask with activated charcoal and exhalation valve fitted)

FFP Class:	**FFP3 NR D**	
Models:	S-367V	(mask with exhalation valve fitted)
	S-367V-AC	(mask with activated charcoal and exhalation valve fitted)

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. «MEDGLOBALFARM» IDNO 1018600000765 REPUBLICA MOLDOVA

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Product Specification (Continued)

Description:	**SR- Series – Conical type disposable face mask with clogging option 7.17**
Technical specification:	**EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles. Classification – Reusable R
FFP Class:	**FFP2 R D**
Models:	SR-S-267V (mask with exhalation valve fitted) SR-S-267V-AC (mask with activated charcoal and exhalation valve fitted)

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Description: **Z- Series - Vertical fold flat disposable face mask with clogging option 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift - NR

FFP Class: **FFP1 NR D**

Models: Z-167

Z-167V (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models: Z-267

Z-267V (mask with exhalation valve fitted)

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA mun. CHISINAU

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Description: **NFK- Series – Conical type disposable face mask with clogging option 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift - NR

FFP Class: **FFP2 NR D**

Models:

NFK-200	
NFK-201	(mask with exhalation valve fitted)
Q-267V	(mask with exhalation valve fitted)

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "MEDGLOBALFARM" S.R.L. IDNO 1016600000765 REPUBLICA MOLDOVA, mun. CHIȘINĂU

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Description: **Z- Series - Vertical fold flat disposable face mask with clogging option 7.17**

Technical specification: **EN 149:2001+A1:2009** Respiratory protective devices – Filtering half masks to protect against particles.
Classification – Single shift - NR

FFP Class: **FFP1 NR D**

Models: Z-167

Z-167V (mask with exhalation valve fitted)

FFP Class: **FFP2 NR D**

Models: Z-267

Z-267V (mask with exhalation valve fitted)

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. «MEDGLOBALFARM» IDNO 1016000000765 REPUBLICA MOLDOVA

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

EU Type Examination Certificate

No. CE 758378

Certificate Administration Details

Technical File Reference:

A - Series: Particle Filtering Half Masks TF1702
C - Series: Particle Filtering Half Masks TF1701
F - Series: Particle Filtering Half Masks TF1704
P - Series: Particle Filtering Half Masks TF1703
S - Series: Particle Filtering Half Masks TF1705
Z - Series: Particle Filtering Half Masks TF1706
NFK Series: Particle Filtering Half Masks TF1707

Certificate Amendment Record

Issue date	Comments
January 2022	First issue.

BSI Internal Project No.

2797:21:3541515

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 758381.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA, mun. CHIȘINĂU

First Issued: 2022-01-11
Latest Issue: 2022-01-11

Effective Date: 2022-01-11
Expiry Date: 2027-01-11

İŞ GÜVENLİĞİ
MEDİKAL A.Ş.

06.09.2023

To: MED GLOBALFARM SRL

Moldova, Chişinău, 2068, str. Miron Costin 17 / 7, of. 71

Authorization Letter

This authorization letter is dated on the 06.09.2023;

MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.

Here in after refer to as "The Exporter" with its principal Office at Hayat Mah., Baruthane Cad. No:21/1, Elvanpazarcık Beldesi 67990, Merkez, Zonguldak, TÜRKİYE

Hereby authorizes **MED GLOBALFARM SRL**

Herein after refer to as "The Distributor"; with its principal place of business at Moldova, Chişinău, 2068, str. Miron Costin 17 / 7, of. 71

To be our distributor in **MOLDOVA REPUBLIC** We certify that The Distributor has been appointed as the marketing holder for **MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.** products range of The Exporter. We here with appoint an authorize The Distributor to be the agent for the registration, import, marketing and selling of our **MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.**

This authorization letter is limited to the procedures in The Territory, The Distributor is not entitled to sub-delegate these tasks and to authorize any other person on the behalf of The Exporter.

This letter is effective starting from the 06.09.2023 and valid untill 07.09.2025

The present letter can be terminated any time with a one-month's written notice period.

Best regards,

MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.

Fatih FURTUN,
General Manager

Hayat Mahallesi Baruthane Caddesi No: 21 /1, 67990
Elvanpazarcık Beldesi Merkez, Zonguldak / TÜRKİYE
Tel : +90 372 253 40 30 Fax : +90 372 253 40 69
www.mfamask.com E-Posta: info@mfamask.com

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Medglobalfarm SRL, cu sediul mun.Chişinău, str. Miron Costin 17/7,of.71,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:
Respiratoar cu valva respiratory FFP2

Sunt autentice şi corespund realităţii.

Director general Granaci Boris

Semnătura _____

Data 08.09.2023