

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

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

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

Solicitantul **IM "Vivamed International" SRL**, cu sediul **Mun. Chișinău, str. Mircea cel Bătrân 16, tel./fax: 022-92-68-01/e-mail: info@vivamed-int.com**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Masca de examinare simpla

Se anexează următoarele acte:
Certificatul CE;
Declaration of Conformity;
Actul prin care producătorul își desemnează reprezentantul.

Data 17.09.2023



Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **IM „Vivamed International” SRL** cu sediul **Mun. Chișinău, str. Mircea cel Bătrân 16,**

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Masca de examinare simpla	B2910
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Sunt autentice și corespund realității.

Director Beregoi V.

Semnătura

Data 17.09.2023

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
		Masca de examinare simpla	Carestone Medical & Protective Products Co., LTD.	B2910	



CARESTONE MEDICAL & PROTECTIVE PRODUCTS CO., LTD.

1.3 SQ. KM. Industrial Garden, Development Zone, Anqing City, Anhui Province, China

Tel: +86-556-529 0167 / 0168 / 0169 E-mail: info@carestonemed.com

Authorization

Date: Sep. 15, 2023

Subject: Registration of medical devices

We, Carestone Medical & Protective Products Co., Ltd. located 1.3 SQ. KM. Industrial Garden, Development Zone, Anqing City, Anhui Province, P.R. China

assign IM Vivamed International SRL, situated on 16, Mircea cel Batrin Rd., Chisinau MD-2044, Republic of Moldova as authorized representative in correspondence with the conditions of directive 93/42/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices we supplied in the territory of the Republic of Moldova.

Place/Date: Anqing

for and on behalf of

CARESTONE MEDICAL & PROTECTIVE
PRODUCTS CO., LTD.

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Name: Robert Yan *Authorized Signature(s)*

Position: M. D.





Verification of Conformity

Applicant: CARESTONE MEDICAL & PROTECTIVE PRODUCTS CO., LTD.
Address: 10F, Bldg13, Guangcaihuijie, Tianzhushan East Road, Anqing City, Anhui Province, China
Product(s): Shoe Cover, Boot Cover, Sleeve Cover, Coverall, Apron, PE Glove, Rain Coat, PE Hood, PE Pants, Shower Cap, Vinyl Glove, Latex Glove, Nitrile Glove, Endoscope Hood Set, Pouch, Cap, Face Mask, Beard Cover, Isolation Gown, Surgical Gown, Scrub Suit, Lab Coat, Mattress Cover, Bed Sheet, Pillow Case, Non woven Roll, Bandage, Hairband, Ear Cover, Dental Bibs, Kimono, Identification Bracelet, Bikini, Under Pad, Slipper, Kidney Tray, Urinal, Respirators, Goggles
Type(s): See Annex of details
Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016;
EN 1041:2013; EN ISO 10993-12009/AC:2010;
EN ISO 10993-5:2009; EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

SUNGO Cert GmbH



Executive Director
Issued: Aug. 7 2019
Cert. No.: EU128518
Expiration Date: Aug. 6 2024



Annex to Cert. No.: EU128518

Product Name	Type
Shoe Cover	14X36cm, 14X38cm, 14X39cm, 14X40cm, 14X41cm, 14X51cm, 14.5X36cm, 14.5X38cm, 14.5X39cm, 14.5X40cm, 14.5X41cm, 14.5X51cm, 15X36cm, 15X38cm, 15X39cm, 15X40cm, 15X41cm, 15X50cm, 15X51cm, 17X40cm, 17X41cm, 18X42cm, or as required
Boot Cover	S,M,L,WITH TIES,WITH ELASTIC,or as required
Sleeve Cover	20X40CM, 20X42CM, 20X43CM, 20X44CM, 20X45CM, 20X50CM, 22X40CM, 22X42CM, 22X43CM, 22X44CM, 22X45CM, 22X50CM, 25X40CM, 25X42CM, 25X43CM, 25X44CM, 25X45CM, 25X50CM,Or as required
Coverall	S,M,L,XL,XXL,XXXL,150X220CM,or as required
Apron	70X110CM,76X110CM,80X110CM,80X125CM,80X130CM,80X140CM,80X160CM,90X170CM,120X90CM,or as required
PE Glove	S,M,L
Rain Coat	S,M,L,XL,XXL,XXXL,XXXXL
PE Hood	105X125+25CM, 85X125+25CM, 72.5X84+25CM, or as required
PE Pants	70*120cm, 70*125cm, 70*150cm, 70*170cm, 75*120cm, 75*125cm, 75*150cm, 75*170cm 80*120cm, 80*125cm, 80*150cm, 80*170cm, 85*120cm, 85*125cm, 85*150cm, 85*170cm 86*120cm, 86*125cm, 86*150cm, 86*170cm, or as required
Shower Cap	S,M,L, or as required
Vinyl Glove	S,M,L
Latex Glove	S,M,L
Nitrile Glove	S,M,L
Endoscope Hood Set	UK design with 2 hoods, DE design with 1 hood, Or as required
Pouch	Sterilization Roll (Reel), Self sealing Sterilization Pouch, Sterilization Gusset Pouches in Roll, Sterilization Heat-Sealable Pouch, Tyvek Sterilization Pouches & Roll
Cap	18", 21", 24", 64X12CM, S, M, L, or as required
Face Mask	1ply, 2ply, 3ply, 4ply
Beard Cover	18", 21", 24", or as your required
Isolation Gown	110X120CM,115X137CM,120X140CM,130X150CM,140X150CM, Or as required
Surgical Gown	125X150CM,130X150CM,140X160CM,150X160CM,160X160CM, Or as required
Scrub Suit	S, M, L, XL, 2XL,3XL,4XL,5XL,6XL,or as required
Lab Coat	S(100 x 130), M(103 x 136), L(107 x 142), XL(110 x 148), XXL(112 x 156), XXXL(116 x 162), or as required
Mattress Cover	200*90+20cm, Special specifications can be customized.
Bed Sheet	80*200cm,140*240cm, or as requested
Pillow Cover	48*27cm, or as required
Non woven Roll	80CMX200M, 120CM * 200M, or as required
Bandage	1.Elastic cotton gauze bandage, cotton yarn:21s,32s,40s;mesh:22,20,18,17,13,12 threads etc. 2.100% cotton bandage, Width:2.5cm,5cm,7.5cm,10cm,15cm,20cm max. Length: 4m, 5m, 10m.or as required
Hairband	4" x 5.5"(not stretch) , stretch up to 13" Special specifications can be customized.
Ear Cover	8cm, 8.5cm, Special specifications can be customized.
Dental Bibs	13" X 18"- 2ply, 13" X 18"- 3ply,Special specifications can be customized.
Kimono	100x140cm, 20-50gsm, Special specifications can be customized.
Identification Bracelet	1.9x25cm, 2.5x25cm, 1.9*25.5cm,Special specifications can be customized.
Bikini	Women - (18x5)x47cm, Man - (21+4)x51cm, Special specifications can be customized.
Under pad	33x45cm, 45x60cm, 60x60cm, 60x90cm, 80x90cm, 80x150cm,100x220cm Special specifications can be customized.
Slipper	11x28cm open toe, 11x28cm close toe, Special specifications can be customized.
Kidney Tray	500-750ml, Special specifications can be customized
Urinal	500-1000ml, Special specifications can be customized
Respirators	FFP1 with or w/o valve, FFP2 with or w/o valve, FFP3 with or w/o valve
Goggles	16*5.5*11.5cm, with multi-holes, 41g/pc, Special specifications can be customized

END OF THE ANNEX



EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Carestone Medical & Protective Products Co., Ltd.
1.3 Sq. Km. Industrial Gardon, Anqing Development Zone, Anhui, China

SRN: CN-MF-000027756

European Representative Luxus Lebenswelt GmbH
Kochstr .1, 47877, Willich, Germany
Tel :0049-1715605732 E-mail: info.m@luxuslw.de

SRN: DE-AR-000005110

Trade Name: Disposable medical face mask

Product Name: Disposable medical face mask

Specification: 17.5x9.5cm, 14.5x9cm

Product Code/Catalogue Number: B2020, B3550, B7201

Basic UDI-DI: 697549344MASKSTT

Classification According to MDR Ax. VIII: Class I, rule 1

Applied Standard & Common Specification:
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041: 2008+A1: 2013
EN ISO 10993-1:2020 EN ISO 10993-5:2009
EN ISO 10993-10: 2013
EN 62366-1: 2015
EN 14683:2019+AC: 2019

Conformity Assessment Procedure: Annex II + Annex III of Regulation EU 2017/745 (MDR)

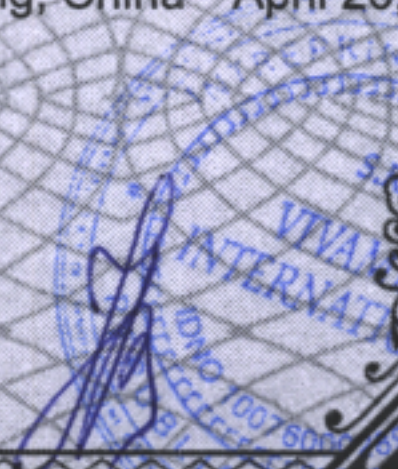


We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

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Yan Wei, General manager

Anqing, China April 26, 2023





This is to certify that the Quality Management System of

Carestone Medical & Protective Products Co., Ltd.

Unified Social Credit Code: 91340800784906811E

Operation Address: 10Fl., Bldg. 13, Guangcaihuijie, Tianzhushan East Road, Anqing City, Anhui Province, China

Registered Address: 1.3 SQ. KM. Industrial Garden, Development Zone, Anqing City, Anhui Province, China

applicable to

Sales of Non-sterile Disposable Plastic Products(Shoe Cover, Boot Cover, Sleeve Cover, Coverall, Apron, Endoscope Hood Set, Mattress Cover, PE Gloves, Vinyl Gloves, Latex Gloves, Nitrile Gloves), Disposable Non-woven Products(Caps, Masks, Sleeve Cover, Isolation Gown, Surgical Gown, Lab Coat, Coverall, Shoe Cover, Boot Cover) and Bandages (Exported to Europe and America)

The other organization applying for certification is: Aobang Healthcare Co., Ltd.

Address: Plant 18, Yingdeli Industrial Park, Yixiu District, Anqing City, Anhui Province, China(Production); 10Fl., Bldg. 13, Guangcaihuijie, Tianzhushan East Road, Anqing City, Anhui Province, China(Office)

Scope: The Production and Sales of Non-sterile Disposable Plastic Products(Shoe Cover, Boot Cover, Sleeve Cover, Coverall, Apron, Endoscope Hood Set, Mattress Cover); The Production and Sales of Disposable Non-woven Products(Caps, Masks)(Exported to Europe and America); Commissioned production and Sales of Disposable Plastic Products(PE Gloves, Vinyl Gloves, Latex Gloves, Nitrile Gloves), Disposable Non-woven Products(Sleeve Cover, Isolation Gown, Surgical Gown, Lab Coat, Coverall, Shoe Cover, Boot Cover) and Bandages(Exported to Europe and America)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

N. Wang

Managing Director



Certificate Number

129630

Date:

30 March 2021

Valid Until:

30 March 2024

EAC Code:

14/04/29



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.



This is to certify that the Quality Management System of

Carestone Medical & Protective Products Co., Ltd.

Unified Social Credit Code: 91340800784906811E

Operation Address: 10Fl., Bldg. 13, Guangcaihuijie, Tianzhushan East Road, Anqing City, Anhui Province, China

Registered Address: 1.3 SQ. KM. Industrial Garden, Development Zone, Anqing City, Anhui Province, China

applicable to

Sales of Non-sterile Disposable Plastic Products(Shoe Cover, Boot Cover, Sleeve Cover, Coverall, Apron, Endoscope Hood Set, Mattress Cover, PE Gloves, Vinyl Gloves, Latex Gloves, Nitrile Gloves), Disposable Non-woven Products(Caps, Masks, Sleeve Cover, Isolation Gown, Surgical Gown, Lab Coat, Coverall, Shoe Cover, Boot Cover) and Bandages (Exported to Europe and America)

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has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

N. Wang

Managing Director

Certificate Number

129631

Date:

30 March 2021

Valid Until:

30 March 2024



015



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

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