

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: 022-92-68-01/022-92-68-02, 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:

Bonete chirurgicale barbati
Bonete chirurgicale barbati cu banda absorbanta
Bonete medicale bufante
Bonete chirurgicale femei
Halate nesterile mărimea S
Halate nesterile mărimea M
Halate nesterile mărimea L
Halate nesterile mărimea XL
Halate nesterile mărimea XXL
Halate nesterile mărimea XXXL
Bahile de unica folosinta
Halat Chirurgical eurostandart ranforsat XL
Halat Chirurgical eurostandart ranforsat XXL
Halata chirurgical steril ranforsat S
Halata chirurgical steril ranforsat L
Halata chirurgical steril ranforsat M
Halata chirurgical steril ranforsat XL
Halata chirurgical steril ranforsat XXL
Halat chirurgical steril S
Halat chirurgical steril M
Halat chirurgical steril L
Halat chirurgical steril XL
Halat chirurgical steril XXI

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	

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
		Bonete chirurgicale barbati	Carestone Medical & Protective Products Co., LTD.	A2300	
		Bonete chirurgicale barbati cu banda absorbanta	Carestone Medical & Protective Products Co., LTD.	A2390	
		Bonete medicale bufante	Carestone Medical & Protective Products Co., LTD.	A2085	
		Bonete chirurgicale femei	Carestone Medical & Protective Products Co., LTD.	A2400	
		Halate nesterile mărimea S	Carestone Medical & Protective Products Co., LTD.	H4200	
		Halate nesterile mărimea M	Carestone Medical & Protective Products Co., LTD.	H4300	
		Halate nesterile mărimea L	Carestone Medical & Protective Products Co., LTD.	H4400	
		Halate nesterile mărimea XL	Carestone Medical & Protective Products Co., LTD.	H4500	
		Halate nesterile mărimea XXL	Carestone Medical & Protective Products Co., LTD.	H4600	
		Halate nesterile mărimea XXXL	Carestone Medical & Protective Products Co., LTD.	H4700	
		Bahile de unica folosinta	Carestone Medical & Protective Products Co., LTD.	L1000	
		Halat Chirurgical eurostandart ranforsat XL	Carestone Medical & Protective Products Co., LTD.	H6750	
		Halat Chirurgical eurostandart ranforsat XXL	Carestone Medical & Protective Products Co., LTD.	H6760	
		Halata chirurgical steril ranforsat S	Carestone Medical & Protective Products Co., LTD.	H6725	
		Halata chirurgical steril ranforsat L	Carestone Medical & Protective Products Co., LTD.	H6745	
		Halata chirurgical steril ranforsat M	Carestone Medical & Protective Products Co., LTD.	H6735	
		Halata chirurgical steril ranforsat XL	Carestone Medical & Protective Products Co., LTD.	H6755	
		Halata chirurgical steril ranforsat XXL	Carestone Medical & Protective Products Co., LTD.	H6765	
		Halat chirurgical steril S	Carestone Medical & Protective Products Co., LTD.	H6520	
		Halat chirurgical steril M	Carestone Medical & Protective Products Co., LTD.	H6530	
		Halat chirurgical steril L	Carestone Medical & Protective Products Co., LTD.	H6540	
		Halat chirurgical steril XL	Carestone Medical & Protective Products Co., LTD.	H6550	
		Halat chirurgical steril XXL	Carestone Medical & Protective Products Co., LTD.	H6560	



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:

Bonete chirurgicala barbati	A2300
Bonete chirurgicala barbati cu banda absorbanta	A2390
Bonete medicale bufante	A2085
Bonete chirurgicale femei	A2400
Halate nesterile mărimea S	H4200
Halate nesterile mărimea M	H4300
Halate nesterile mărimea L	H4400
Halate nesterile mărimea XL	H4500
Halate nesterile mărimea XXL	H4600
Halate nesterile mărimea XXXL	H4700
Bahile de unica folosinta	L1000
Halat Chirurgical eurostandart ranforsat XL	H6750
Halat Chirurgical eurostandart ranforsat XXL	H6760
Halata chirurgical steril ranforsat S	H6725
Halata chirurgical steril ranforsat L	H6745
Halata chirurgical steril ranforsat M	H6735
Halata chirurgical steril ranforsat XL	H6755
Halata chirurgical steril ranforsat XXL	H6765
Halat chirurgical steril S	H6520
Halat chirurgical steril M	H6530
Halat chirurgical steril L	H6540
Halat chirurgical steril XL	H6550
Halat chirurgical steril XXI	H6560

Sunt autentice și corespund realității.

Director Beregoi V.

Semnătura

Data 17.09.2023



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.

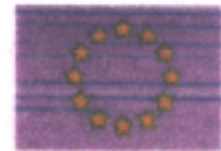
Place/Date: Anqing
for and on behalf of
CARESTONE MEDICAL & PROTECTIVE
PRODUCTS CO., LTD.

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Name: Robert Yan *Authorized Signature(s)*
Position: M. D.



CERTIFICATE ◆ ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ 認證證書 ◆



European Commission

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



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



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: Caps

Product Name: Caps

Specification: 17", 18", 19", 20", 21", 24", 64*12cm, S, M, L

Product Code/Catalogue Number: A0500, A1000, A1100, A1200, A1300, A1500
A2000, A2060, A2085
A2300, A2400

Basic UDI-DI: 697549344CAPSQS

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

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

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.

严伟

Yan Wei, General Manager

Anqing, China April 26, 2023



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, Wilich, Germany
Tel :0049-1715605732 E-mail: info.m@luxuslw.de

SRN: DE-AR-000005110

Trade Name: Isolation Gown

Product Name: Isolation Gown

Specification: S-110*110cm, M-110x120cm, L-115x137cm, XL-120x140cm,
XXL-130x150cm, XXXL-140x150cm, as per required

Product Code/Catalogue Number: H4200, H4300, H4400, H4500, H4600, H4700

Basic UDI-DI: 697549344ISOLATIONGOWNS6R

Classification Acc. 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

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

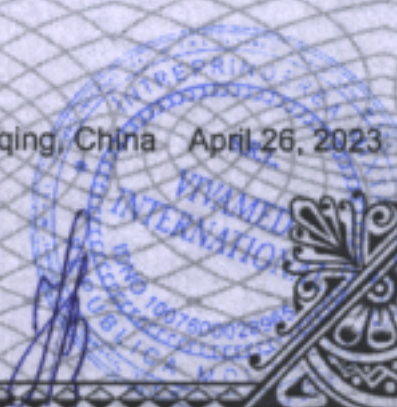


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Yan Wei, General Manager

Anqing, China April 26, 2023



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: Reinforced Surgical Gown

Product Name: Reinforced Surgical Gown

Specification: S - 117*140cm, M - 125*145cm, L- 132*150cm, XL-140*155CM
XXL - 150*160cm, XXXL - 160*160cm or as per required

Product Code/Catalogue Number: E3505, E3515, E3525, E3535, E3555, E3565

Basic UDI-DI: 697549344SURGICALGOWNSUC

Classification Acc. 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

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



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: Shoe Cover

Product Name: Shoe Cover

Product Code/Catalogue Number: L0200, L0250, L0500, L0550, L0600, L0650, L0700, L0750,
L0800, L0850, L1000, L1050, L1200, L1250, L1500, L1550,
L1700, L1750, L2000, L2050, L2500, L2600

Basic UDI-DI: 697549344SHOECOVERS93

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

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 May 26, 2023



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: Surgical Gown

Product Name: Surgical Gown

Specification: S - 117*140cm, M - 125*145cm, L- 132*150cm, XL-140*155CM
XXL - 150*160cm, XXXL - 160*160cm or as per required

Product Code/Catalogue Number: E2500, E2600, E2700, E2800, E2900, E3000

Basic UDI-DI: 697549344SURGICALGOWNSUC

Classification Acc. 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

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



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Yan Wei, General Manager

Anqing, China April 26, 2023

