

MED+Docare

FOOT PROTECTION

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Foot Protection

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ISO 9001:2008 ISO 13485:2003 CE/TUV/FDA

Certificate of Registration



This is to certify that the Quality Management System of
Wuhan Meddicare Disposable Products Co., Ltd.
 Open Economic Zone, Nantian, Hubei Province, China
 has been assessed and registered by nqa against the provisions of
ISO 13485:2003

For the manufacture and supply of the following products:
 Sterile non-sterile medical products including face masks,
 normally patient gloves, ball caps, heel slippers, caps, shoe covers, shoe covers,
 aprons, under pants, disposable non-woven dental products including dental caps,
 dental bibs, dental aprons, dental aprons, dental examination gowns and disposable
 sterile dental gloves (the export only).

The registration is subject to the company establishing a quality management system in
 accordance with the requirements of the requirements of the
 CE marking according to Annex I & II of the 93/42/EEC Medical Device Directive
 (including MDD/IVDR).

The scope of the included products is subject to the CE marking in the
 scope of the CE marking and is limited to the CE marking in the scope of the
 CE marking and is subject to the CE marking in the scope of the CE marking.

For nqa:
 Signed: Tony Chea
 General Manager (Registration)



Compliance Report

Product: Disposable face mask, Disposable cap, Disposable gown, Disposable shoe cover, Disposable apron, Disposable bib, Disposable dental cap, Disposable dental apron, Disposable dental examination gown, Disposable dental gloves (the export only).

The intended system (the including test report of the above products have
 been assessed against the CE marking requirements of compliance for CE
 marking according to Annex I & II of the 93/42/EEC Medical Device Directive
 (including MDD/IVDR).

The scope of the included products is subject to the CE marking in the
 scope of the CE marking and is limited to the CE marking in the scope of the
 CE marking and is subject to the CE marking in the scope of the CE marking.

For nqa:
 Signed: Tony Chea
 General Manager (Registration)



Assess to Report (No. 82219)

Wuhan Meddicare Disposable Products Co., Ltd.

Product Name	Type
Disposable face mask	ISO 13485:2003 (2003)
Disposable cap	ISO 13485:2003 (2003)
Disposable gown	ISO 13485:2003 (2003)
Disposable shoe cover	ISO 13485:2003 (2003)
Disposable apron	ISO 13485:2003 (2003)
Disposable bib	ISO 13485:2003 (2003)
Disposable dental cap	ISO 13485:2003 (2003)
Disposable dental apron	ISO 13485:2003 (2003)
Disposable dental examination gown	ISO 13485:2003 (2003)
Disposable dental gloves (the export only)	ISO 13485:2003 (2003)

The above is only a brief summary of the report assessment details.

CE Technical Documentation Review Report

Client: Wuhan Meddicare Disposable Products Co., Ltd.
 Open Economic Zone, Nantian, Hubei Province, China

Report Number: 2580229-01

Examination scope: Examination of the completeness of the Technical Documentation according to the requirements of the Medical Device Directive (2006/42/EC Annex V)

Product(s): Non-sterile medical non-woven products:

- Goggles
- Caps
- Face masks
- Surgical gowns

Classification: Class I (according to manufacturer's declaration)

Examination period: 02/27/2015
Date of expiry: 02/23/2016

Review result: Due to the examination of the provided Technical Documentation (No.: DC-2013CE1, DC-2013CE2, DC-2013CE3, version 01, dated Sep. 14, 2013), we find compliance according to the requirements of the Medical Device Directive (2006/42/EC Annex V) is achieved.

TUV Product (China) Ltd. Being Operated

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 2012Q0009R004328

We hereby certify that **WUHAN MEDDICARE DISPOSABLE PRODUCTS CO., LTD.**
 Open Economic Zone, South of Xiangyuan City, Hubei, China
 No. 88, #28th St., Xiangyuan City, Hubei, China
 has been awarded this certificate for compliance with the standard **ISO9001:2008 GB/T 19001-2008**
 The Quality Management System Applied to the following area:
 Manufacture and Service of Disposable Medical Products: Face Mask, Shoe Cover, Gown, Cap, Apron, Bib, Cap, Goggles, etc.

Certification and Development Registered
 Certificate valid from **May 01, 2015** to **May 30, 2018**
 Valid until **May 30, 2018**

China Quality Certification Centre

Fiscal Year 2015 CERTIFICATION OF REGISTRATION

The certifier is:

WUHAN MEDDICARE DISPOSABLE PRODUCTS CO., LTD.
 Open Economic Zone, Nantian, Hubei Province, China 430000

Has obtained the FDA Establishment Registration for manufacture and Foreign distribution and Distribution (CDMO) with the US Food & Drug Administration, through:

MedDevice Services, LLC

Owner/Operator Number: 10649049

Device Listing:

Listing No.	Code	Device Name
CDMO4	6161	MAXI, SCISSOR-TYPE GOWN (non-sterile face mask)
CDMO7	7317	CLASS II MEDICAL (surgical cap, headdress cap)
CDMO4	6161	REPT BIOLOGICAL ISOLATION GOWN (sterile gown, full cover)
CDMO4	7317	COVER, APRON, OPERATING ROOM (sterile gown)
CDMO7	1717	NECESSARY, BIOLOGICAL APPAREL (sterile gown)

meds+
 MedDevice Services, LLC
 1000 South Capital Highway, Suite 1000, Columbia, SC 29201, USA
 Tel: +1 803 763 1000 Fax: +1 803 763 1000
 www.meddevice.com www.medsplus.com

Care Shoe-Disposable Non-woven Shoe Cover

Material: Polypropylene, Non-woven PP/PP+PE/PP+CPE fabric

Color: White/blue/green/yellow, etc. Weight: 20-55GSM

SIZE: S 15x38cm, M 15x40cm, L 17x40cm, XL 17x43cm

Item No.:

Packing:

**PPHH
PPFH
PP1M
PP2M**

**PPEH
PCPE
PPEM**

**10pcs/roll, 10 rolls/bag, 10 bags/ctn;
10pcs/roll, 10 rolls/bag, 20 bags/ctn.**



Care Shoe-Disposable Non-slip Shoe Cover

Material: Polypropylene, Non-woven fabric

Color: White/blue, etc. Weight: 25-55GSM

**SIZE: S 15x38cm, M 15x40cm,
L 17x40cm, XL 17x43cm**

Item No.: Packing:

**PPASH
PPASM**

**10pcs/roll, 10 rolls/bag, 10 bags/ctn;
10pcs/roll, 10 rolls/bag, 20 bags/ctn.**



Care Shoe-Disposable PE/CPE Shoe Cover

Material: Polyethylene, PE/CPE fabric

Color: White/blue/green/yellow, etc. **Weight:** 1.5-11G.

SIZE: S 15x38cm, M 15x40cm, L 17x40cm, XL 17x43cm



Item No.:

Packing:

PEM
PEH
CPEM
CPEH

10pcs/roll, 10 rolls/bag, 10 bags/ctn;
10pcs/roll, 10 rolls/bag, 20 bags/ctn.



Care Shoe-Disposable PP+CPE Shoe Cover

Material: Non-woven covered with CPE fabric

Color: White/blue Weight: 9-20GSM

**SIZE: S 15x38cm, M 15x40cm,
L 17x40cm, XL 17x43cm**

Item No.:

Packing:

PCPE

**10pcs/roll, 10 rolls/bag, 5 bags/ctn;
10pcs/roll, 10 rolls/bag, 10 bags/ctn.**

