

An operating room with two large surgical lights hanging from the ceiling. The lights are illuminated, casting a bright glow. The room is clean and modern, with white walls and a light-colored floor.

MED+DOCARE

OTHER PROTECTION

www.meddocare.com 2016



MED+Docare

Other Protection

Disposable Bed Sheet	03
Disposable Mattress Cover	04
Disposable Pillow Case	05
Disposable Dental Bib	06
Disposable Under Pad	07

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
 (Registration No. 0001) has been found to conform to the requirements of the
 following standards:
ISO 13485:2003
 The registration is subject to the company establishing a quality management system in
 accordance with the requirements of the standards listed above. The registration will be reviewed by NQA
 at intervals of six months and for duration of 30 months from completion
 of the registration.
0001
 Issued: 11 July 2014
 Valid Until: 11 July 2015
 SAC Code: 14





Compliance Report

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

Notes: Disposable face mask, Disposable Contact,
 Disposable surgical gown, Disposable Lab Coat,
 Disposable face shield, Disposable cap,
 Disposable shoe cover, Disposable face mask,
 Disposable apron, Disposable under pad,
 Disposable facial product, Disposable patient gown
 for area for block

Product Description: Class I

The registered system, the including test report of the above products have
 been reviewed against the self-declaration requirements of standards for CE
 marking according to Annex I & II of the 2007/45/EC Medical Device Directive
 (including MDD/2007/45/EC).

The scope of the included items will be subject to the self-declaration by
 the device label sheet. The test report and the product file on the scope of the
 items will also be used for audit.

Where the registration is subject to the self-declaration for product label sheet
 audit that is subject to the appropriate CE declaration form and evidence
 to be used.

The effective date of registration is 11 July 2014.

For NQA:
 Valid Until: 11 July 2015




Access to Report (No. 000109)

Wuhan Meddicare Disposable Products Co., Ltd.

Product Name	Type
Disposable face mask	Class I
Disposable Contact	Class I
Disposable surgical gown	Class I
Disposable Lab Coat	Class I
Disposable face shield	Class I
Disposable cap	Class I
Disposable shoe cover	Class I
Disposable face mask	Class I
Disposable apron	Class I
Disposable under pad	Class I
Disposable facial product	Class I
Disposable patient gown for area for block	Class I

The above is only a summary of the products included in the report. For more details,
 please refer to the full report available on NQA's website.



CE Technical Documentation Review Report

Applicant: Wuhan Meddicare Disposable Products Co., Ltd.,
 Open Economic Zone, Nantian, Hubei Province,
 430200, P. R. China

Report Number: 20802020101

Examination scope: Examination of the completeness of the Technical
 Documentation according to the requirements of the
 Medical Device Directive (2007/45/EC Annex VI)

Products: Non-sterile medical non-woven products:
 Goggles, Disposable face mask, Cap,
 Face mask, Disposable face shield,
 Surgical gown

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

Examination period: 02.27.2015

Date of expiry: 02.28.2016

Review result: During the examination of the provided Technical
 Documentation (No.: DC-2013CE1, DC-2013CE2,
 DC-2013CE3, version 01, dated Sep. 14, 2013), no
 non-compliance according to the requirements of the
 Medical Device Directive 2007/45/EC Annex VI was
 observed.





**QUALITY MANAGEMENT SYSTEM
 CERTIFICATE**

Certificate No.: 2015CNQ00019044338

We hereby certify that
WUHAN MEDDICARE DISPOSABLE PRODUCTS CO. LTD.
 Open Economic Zone, South of Xiangyang City, Hubei, China
 No. 26, 28, 30, 32, 34, 36, Yangyang Road, Xiangyang District, Wuhan, Hubei, China

is in conformity with the
Quality Management System
 has been awarded this certificate for compliance with the standard
ISO9001: 2008
GB/T 19001-2008
 The Quality Management System applies to the following area:
 Manufacture and Service of Disposable Face Mask, Disposable Face Shield, Cap, Goggles, Shoe Cover,
 Apron, Under Pad and Patient Gown Products

Business Origin and Development Requirement:
 Certificate valid from May 29, 2015 to May 28, 2016. Valid until May 28, 2016



CHINA QUALITY CERTIFICATION CENTRE
 Address: 100000, Beiyinmen East Road, Beijing, P.R. China



**Fiscal Year 2015
 CERTIFICATION OF REGISTRATION**

This certifies that
WUHAN MEDDICARE DISPOSABLE PRODUCTS CO. LTD.
 Open Economic Zone, Nantian, Hubei Province, China 430200

has been found to conform to the requirements of the
 Device Listing with the US Food & Drug Administration, through
MDJ Services, LLC

Owner/Operator Number: 10649049

Device Listing:

Listing No.	Code	Device Name
224024	G401	MAXI, SCISSOR-TYPE GLOVES (non-sterile)
224027	F311	CLASS II SURGICAL GLOVES (sterile)
224024	065A	NON-SURGICAL GLOVES (GOWN) (non-sterile)
224024	F32P	COVER, SHIRT, OPERATING ROOM (sterile)
224027	L31V	NECESSARY, SURGICAL APPLIES (sterile)



MDJ Services, LLC
 1000 South Coast Highway, Suite 1000, Newport, NJ 07424
 Tel: +1-973-262-1000 Fax: +1-973-262-1001
 www.mdjservices.com
 www.fda.gov/oc/ohrt/

Executive Director
 Robert J. Papp
 September 29, 2015

Care Bed-Disposable Bed Sheet

Material: Polypropylene, PP/SMS fabric

Color: White/blue/green, etc. Weight: 20-50GSM.

SIZE: Customized

Item No.:

Packing:

**BSPP
BSMS**

**BSPPE
BSPE**

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

Disposable Mattress Cover MEDDocare

Care Bed-Disposable Mattress Cover

**Material: Polypropylene, PP/SMS fabric;
Polyethylene, CPE fabric**

Color: White/blue/green, etc. Weight: 20-50GSM.

SIZE: Customized

Item No.:

**BSPPE BSPPEE
BSMSE MCPE**

Packing:

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

Care Bed-Disposable Pillow Case

Material: Polypropylene, PP/SMS fabric;

Color: White/blue/green, etc. Weight: 20-50GSM.

SIZE: Customized

Item No.:

**PCPP
PCSMS**

Packing:

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

Disposable Dental Bib

Material: Tissue paper covered with PE

Color: White/blue/green, etc. **Weight:** Standard

SIZE: Customized

Item No.:

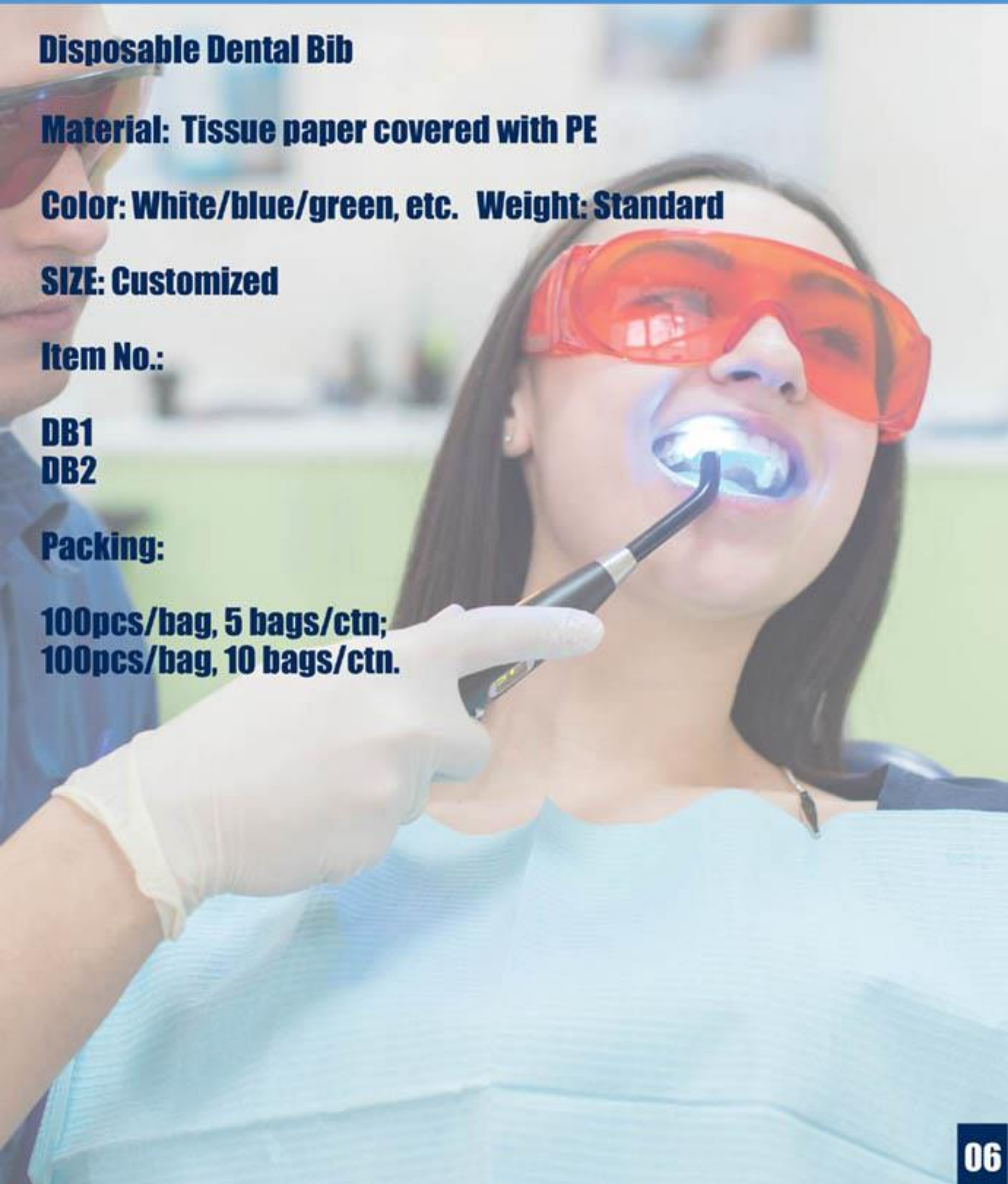
DB1

DB2

Packing:

100pcs/bag, 5 bags/ctn;

100pcs/bag, 10 bags/ctn.



Disposable Under Pad

Material: Tissue paper covered with PE

Color: White/blue **Weight:** Standard

SIZE: Customized

Item No.:

UP1
UP2

Packing:

10pcs/bag, 10 bags/ctn;
10pcs/bag, 15 bags/ctn.

