

# CE Documentation Review



No. OP190508.NAIDU17

Holder:

Medding Medical Products Co., Ltd.  
Via S. Maria, 10 - 40053 Valsamoggia (Bo) Italy  
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Review goal:

Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product:

Disposable Caps, Disposable Face Mask, Disposable Coverall, Disposable Gown, Disposable Lab Coat, Disposable Shoe Covers, Disposable Sleeve Covers, Disposable Apron, Disposable Raincoat, Disposable Bed Sheet, Disposable Bed Cover

Model(s):

(see the following annex I)

Classification:

Class I  
(accordingly to the Manufacturer's declaration)

Review output:

We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. TMJS19042917882. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 08 May 2019

Expiry date 07 May 2024

Chief Manager  
Marco Morina



Deputy Manager  
Amanda Fiume



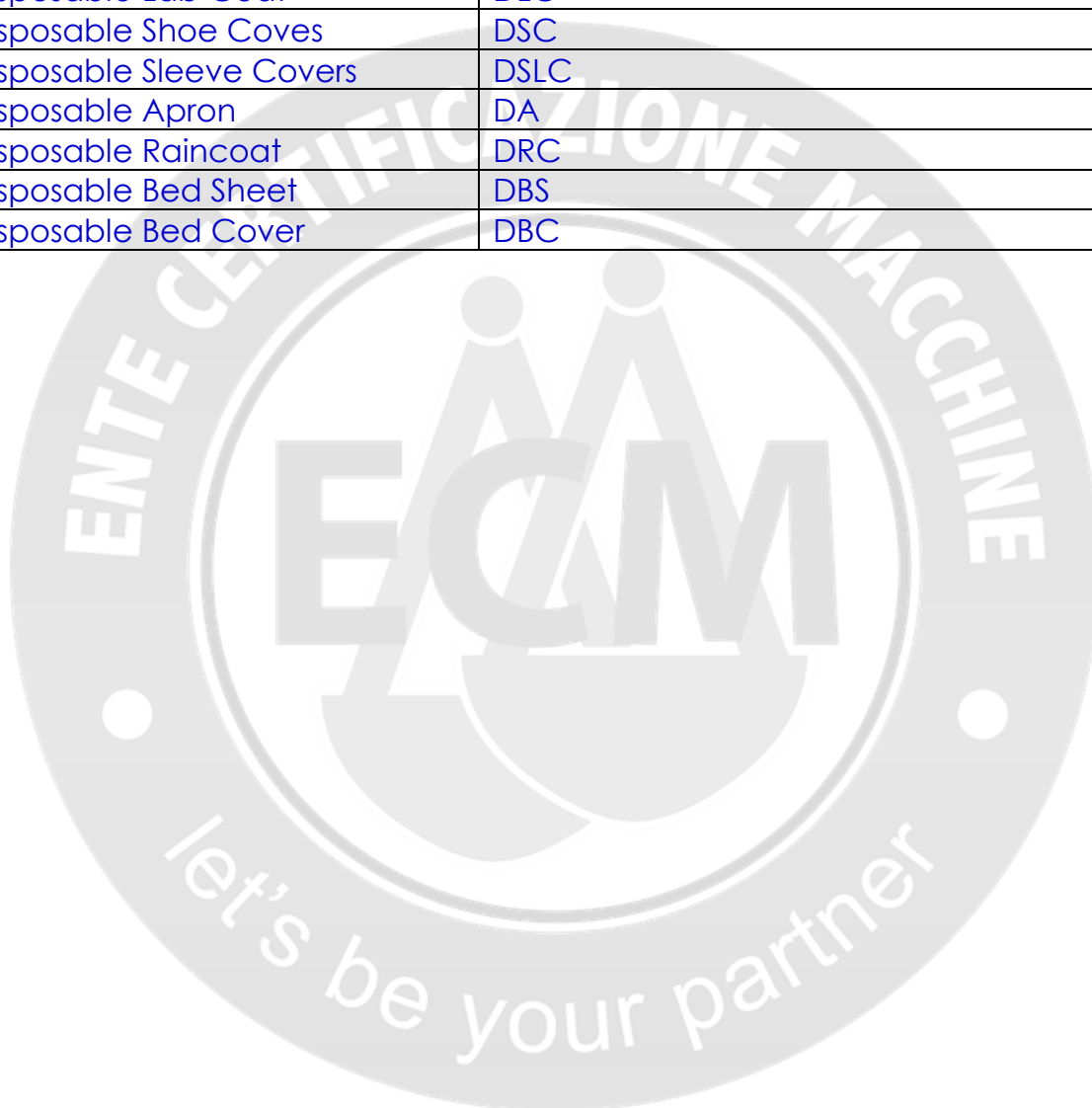
**Ente Certificazione Macchine**

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# Annex I

No. OP190508.NAIDU17

Name	Model/ Type
Disposable Caps	DC
Disposable Face Mask	DFM
Disposable Coverall	DCR
Disposable Gown	DG
Disposable Lab Coat	DLC
Disposable Shoe Coves	DSC
Disposable Sleeve Covers	DSL
Disposable Apron	DA
Disposable Raincoat	DRC
Disposable Bed Sheet	DBS
Disposable Bed Cover	DBC



# Disposable Face Mask

## USER'S MANUAL

**[Taxpayer Identification Number]** 91420984695142514A

**[Product structure and composition]** This product consists of non-woven fabric,filter paper,nose clip,mask band (or rubber band); The mask is made of two layers of non-woven fabric with one layer of filter paper ,folded and welded by ultrasonic.

**[Specifications]** Normal type face mask with rubber band;  
Adult: 17.5cm x 9.5cm;

**[Product Performance]** The appearance of the mask should be correct,the shape should be intact,and the surface should be clean,and there shall be no damage,stain,mildew and peculiar smell. Nose clip length should not be less than 8.0cm. The breaking strength at the connection point between each mask belt and the mask body should not be less than 10N.

**[Scope of Application]** This mask is a single-use product for personal protective use .(This mask cannot be used as a surgical or protective mask)

**[Method of Application]** Open the packing bag to take out the mask.The nose clip is above the mask,with the colored side facing outwards.Cover the nose,mouth and chin with the mask. After fixing the mask strap to the ear,place the tips of your fingers on the bridge of the nose.Press with your hand pointing inward,and gradually move to both sides,shape the nose,adjust the tightness of the tie,and make the mask close to the face.When removing the mask,do not touch the front of the mask,remove the mask band first,only pinch the mask band with your hand and throw it into the waste container.

**[Notes]** 1. Do not use if the packaging is broken.  
2. This product is a one-time use product,it is strictly forbidden to reuse.  
3. Please use immediately when the package is unsealed  
4. The mask can not be used reversibly .  
5. When wearing,the nose should be compacted to prevent leaks.  
6. Replace masks when they become contaminated or damaged.

**[Expiration Date]** This product is valid for 3 years.

**[Storage Conditions]** This product should be stored in a room with a relative humidity of not more than 80%,and no corrosive gas and well ventilated.

Manufacturer: **Hubei Xingxing Protective Products Co., Ltd.**

Production/ Registered address: **10th Floor, 10th Street, Xingxing, Xingxing Industrial City, Hubei Province, China**

# Test Report

Report Number: A2200051280101C

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Applicant: 

Address: 

The following sample(s) and sample information was/were submitted and identified by/on the behalf of the clients .

Sample Name:Mask

Model : 17.5x9.5cm

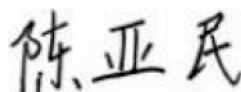
Date of Sample Received: 2020.03.16

Testing Period: 2020.03.06-2020.03.23

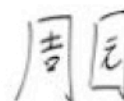
## Test Requested:

Selected test(s) as requested by client. Please refer to next page(s).

Signed for and on behalf of:



Approved Signatory



Approved Signatory

Date: 2020.03.23

No.S385532039

Centre Testing International Group Co.,Ltd

CTI Building, Xin'an Street, Bao'an District, Shenzhen, P.R. China

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Test Result(s)		
Tested Item(s)	Test Standard	Single Conclusion
Appearance requirement	GB/T 32610-2016	Qualified
Color fastness to rubbing	GB/T 29865-2013	Qualified
Formaldehyde Content	GB/T 2912.1-2009	Qualified
pH Value	GB/T 7573-2009	Qualified
Degradable carcinogenic aromatic amine dye	GB/T 17592-2011/ GB/T 23344-2009	Qualified
Breaking strength of the mask belt and the joint between the mask belt and the mask body	GB/T 13773.2-2008	Qualified

Judgment Basis	GB/T 32610-2016
***For detailed results,please refer to next page(s)***	

# Test Report

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Test Requested (Selected test(s) as requested by client)

## 1. Appearance requirement (GB/T 32610-2016)

Tested Item(s)	Result	Standard Request
	001	
Appearance	No Defect	The surface of the mask should be free from damage, oil stains, deformation and other obvious defects.

## 2. Color fastness to rubbing (GB/T 29865-2013)

Tested Item(s)	Result (level)	Standard Request (level)
	002	
Dry friction	Level 4-5	≥ level 4

## 3. Formaldehyde content (GB/T 2912.1-2009)

Tested Item(s)	Result (mg/kg)				MDL (mg/kg)	Standard Request (mg/kg)
	002	003	004	005		
Formaldehyde	N.D.	N.D.	N.D.	N.D.	20	≤20

## 4. pH (GB/T 7573-2009)

Tested Item(s)	Result	Standard Request
	004	
pH Value	6.3	4.0~8.5

Remark: 1. Temperature of extraction solution: 20°C  
2. Type of extraction solution: 0.1 mol/L KCL  
3. pH of 0.1 mol/L KCL: 5.7

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## 5. Degradable carcinogenic aromatic amine dye (GB/T 17592-2011/ GB/T23344-2009)

No.	Tested Item(s)	CAS No.	Result (mg/kg)	MDL (mg/kg)	Standard Request (mg/kg)
			002		
1	4-aminobiphenyl	92-67-1	N.D.	5	≤ 20
2	benzidine	92-87-5	N.D.	5	≤ 20
3	4-chloroo-toluidine	95-69-2	N.D.	5	≤ 20
4	2 - naphthylamine	91-59-8	N.D.	5	≤ 20
5	o-aminoazo-toluene	97-56-3	N.D.	5	≤ 20
6	5-nitro-o-toluidine	99-55-8	N.D.	5	≤ 20
7	Of chloroaniline	106-47-8	N.D.	5	≤ 20
8	2, 4-diaminomethyl ether	615-05-4	N.D.	5	≤ 20
9	4,4' -diaminodiphenylmethane	101-77-9	N.D.	5	≤ 20
10	3,3' -dichlorobenzidine	91-94-1	N.D.	5	≤ 20
11	3,3' -dimethoxybenzidine	119-90-4	N.D.	5	≤ 20
12	3,3' -dimethyl benzidine	119-93-7	N.D.	5	≤ 20
13	3,3'-dimethyl-4,4' -diaminobenzene methane	838-88-0	N.D.	5	≤ 20
14	2-methoxy-5-methylaniline	120-71-8	N.D.	5	≤ 20
15	4,4'-methylene-2-(2-chloroaniline) 3,3'-dichloro-4,4'-diaminobenzene Alkanes)	101-14-4	N.D.	5	≤ 20
16	4,4' -diaminodiphenyl ether	101-80-4	N.D.	5	≤ 20
17	4,4' -diaminodiphenyl sulfide	139-65-1	N.D.	5	≤ 20
18	o-toluidine	95-53-4	N.D.	5	≤ 20
19	2, 4-diaminotoluene	95-80-7	N.D.	5	≤ 20
20	2,4, 5-trimethylaniline	137-17-7	N.D.	5	≤ 20
21	O-aminophenyl methyl ether	90-04-0	N.D.	5	≤ 20
22	4-aminoazobenzene	60-09-3	N.D.	5	≤ 20
23	2, 4-dimethylaniline	95-68-1	N.D.	5	≤ 20
24	2, 6-dimethylaniline	87-62-7	N.D.	5	≤ 20

Remark: - N.D. = not detected (Less than method detection limit)

- mg/kg = ppm = part per million



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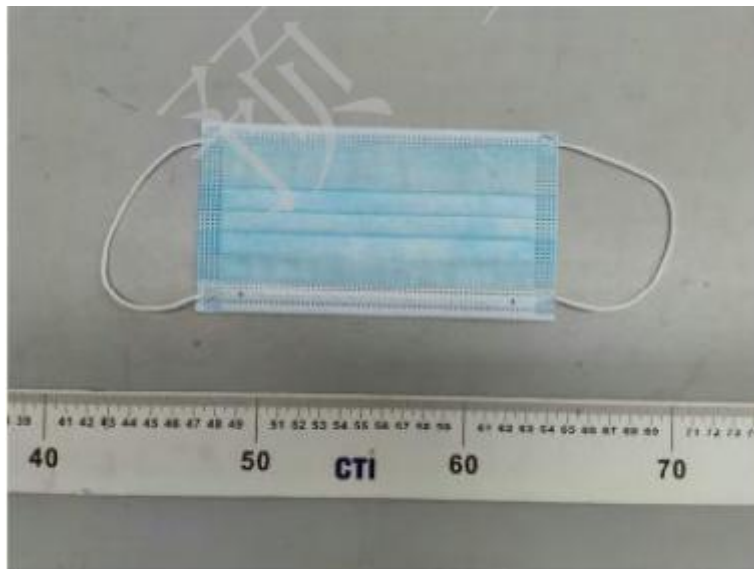
## 6. Breaking strength of the mask belt and the joint between the mask belt and the mask body (GB/T 13773.2-2008)

Tested Item(s)	Result	Standard Request
	001	
Breaking Strength	20.1N	≥20N

### Tested Sample/ Part Description:

- 001 Blue Mask
- 002 Blue Non-woven Fabric ( Surface layer)
- 003 White Non-woven Fabric ( Middle layer)
- 004 White Non-woven Fabric ( Face contact layer)
- 005 White rope (Hanging ear rope)

## Photo(s) of the sample(s)



\*\*\*End of Report\*\*\*

The test report is effective only with both signature and specialized stamp. The result(s) shown in this report refer only to the sample(s) tested. Without written approval of CTI, this report can't be reproduced except in full.