

EC Certificate Full Quality Assurance System: Certificate CN19/41094

The management system of

# Ningbo Chinmed Technology Co., Ltd.

No. 20 Xingzhong Rd, Qijashan Street, Beilun Area, Ningbo,  
Zhejiang Province, 315803, P.R. China

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Sterile hydrocolloid dressings, sterile wound dressings**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 18 January 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 07 December 2015  
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/HGH 5478

Authorised by

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
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LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

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# EC Conformity

*Manufacturer:*

Ningbo Chinmed Technology Co., Ltd.  
Address: No.20 Xingzhong Rd, Qijiashan Street,  
Beilun Area, Ningbo, Zhejiang Province, China

*Authorized Representative:*

Sungo Europe B.V.  
Address: Olympisch Stadion 24,  
1076DE Amsterdam, Netherlands

We, the manufacturer, herewith declare that the products

## Sterile Wound Dressings

*UMDNS-Code:* [11-315]

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **II a** , according to Annex IX of the Directive 93/42/EEC.  
It bears the mark



Following the procedure relating to the EC Declaration of Conformity set out in in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.


The above mentioned declaration of conformity is exclusively under the responsibility of

Manufacture: Ningbo Chinmed Technology Co., Ltd.  
Address: No.20 Xingzhong Rd, Qijiashan Street, Beilun Area, Ningbo, Zhejiang Province, China

2020-2-28

*Place , date*

*For and on behalf of*  
宁波市诚德医疗科技有限公司  
NINGBO CHINMED TECHNOLOGY CO.,LTD.

  
.....  
*Authorized Signature(s)*

*Legally binding signature, Function*



## Material Safety Data Sheet

### 一、 Product and corporate identity

Product name: Dressing pad (Absorbent pad )
Company Name: NINGBO CHINMED TECHNOLOGY CO.,LTD
Contact: No.20 Xingzhong Road, Beilun,Ningbo. China
Tel: 0086-574-83006172 Fax: 86-574-87482209 Email: info@chinmed.cc

### 二、 Ingredient identification data

Pure substance or mixture: pure substance

Product name:	Absorbent Pad
Components:	Polyester fiber, viscose fiber, PE mesh.

### 三、 Risk Overview

Danger level: Not applicable
Harm to human health: no special reaction. Environmental hazards: undetectable Physical and chemical hazards: undetectable Special hazard: undetectable
Unable to detect major symptoms
Observation of emergencies: no data

### 四、 First-aid

Inhalation: usually not possible
Skin contact: If redness, swelling, itching, air bubbles, etc. occur, stopusing it immediately and seek medical attention if serious.
Eye contact: Rinse immediately with water and seek medical attention ifserious.
Ingestion: Vomit immediately and seek medical advice in a timely manner.
Most important symptoms and effects: No special reactions
Protection for first aid personnel: None
Tips for physicians: None

### 五、 Fire-fighting measures

Suitable fire extinguishing agent:	water, carbon dioxide, dry powder fire
Unsuitable extinguishing agents:	None
Special hazards you may encounter during fire fighting:	smoke irritation
Special Fire Fighting Procedures:	None
Special protective equipment for fire-fighters:	Wear a gas mask if necessary

## 六、Emergency response

Personal protection measures: no possibility of leakage

Environmental precautions: no possibility of leakage

Methods to prevent leakage:

Neutralization: No possibility of leakage

Treatment: No possibility of leakage

## 七、Handling and storage

Disposal technical measures:

Preventive measures: None

Note: Avoid high temperature

Storage conditions: Avoid direct sunlight, store in a dry, clean place, storage temperature 0 °C ~ 40 °C.

## 八、Leak prevention measures

Personal protective equipment: Not required

Hand care: no need

Eye Care: Not Required

Skin and body protection: Not required

## 九、Physical and chemical properties

Material properties

Appearance: pieces                      color: skin tone or transparent

Odor: Negligible                          pH: Undetectable

Chemical properties:

Sinopec polyester fiber CAS code 25038-59-9

LANZING NANJING Viscose CAS code 68442-85-

DelStar PE Omentum CAS Code 9002-88-4

Boiling point /boiling point              range: Undetectable Melting point (° C): 235 ° C

Decomposition temperature: not detectable              Flash point: not detectable

Spontaneous combustion temperature: 462 ° C              Explosion limit: Undetectable

Steam pressure: not detectable              Steam temperature: not detectable

Density: Undetectable                          Solubility: Undetectable

Separation coefficient of octanol and water: undetectable

## 十、Stability and reactivity

Stability: stable at normal temperature