

Material Safety Data Sheet (物料安全说明书)**SECTION I Product & Manufacturing Information 产品和生产商信息**

Material Name (物料名称): PU Film (PU 薄膜卷)
Application: Skin care after tattoo (纹身后的皮肤护理)
Product Specification: 10cm*10m, 15cm*10m, 20cm*10m, 10cm*15cm
Manufacture Name & Address (供应商名称和联系资料):
Ningbo Chinmed Technology Co., Ltd
宁波市诚德医疗科技有限公司
Tel: +86-0574-87905316
Email: Sales08@chinmed.cc
Add: No.20 Xingzhong Rd, Qijiashan Str, Ningbo 315010 China
地址: 宁波北仑区戚家山联合开发区兴中路 20 号

SECTION II Raw Material Information 原材料信息

Chemical Ingredient (化学成分 1): Polyurethane (聚氨酯)
Chemical Ingredieint (化学成分 2): Acrylics Adhesives (医用丙烯酸胶水)
Chemical Ingredient (化学成分 3): Glassine paper with silicone (格拉辛纸和硅)
Chemical Ingredient (化学成分 4): Polyethylene (聚乙烯)
Foe Ingredient (危害成分): No, 无

SECTION III Hazard Information 有害物质信息 (Normal Temperature) (常温状态下)

Ingestion(摄取)	Inhalation(吸入)	Skin Contact (皮肤接触)	Eye Contact(眼睛接触)
No	No	Yes	---

Emergency And First Aid Procedure Aid Procedures (紧急情况和急救措施):

For skin sensitive person, maybe who will be sensitive to product:

对一些皮肤敏感者, 可能会有皮肤过敏现象发生。

If appears anaphylactic reaction, must stop to use and ask for doctor.

出现过敏现象时, 立刻停止使用, 情况严重时请就医。

SECTION IV Fire and Explosion Hazard Data (火灾与爆炸危险信息)

Fire Extinguisher (灭火器): Normal Fire Extinguisher (通用灭火器)
Special Fire Fighting (特殊灭火装置): No need(不需要)
Unusual Fire and Explosion Hazard (非常火情与爆炸危害): No (无)
Fire Control & Special Defend Step (火情控制与特殊抵抗步骤): fire extinction method (通用灭火方式)

SECTION V Spill or Leak Procedure (溢出或泄露处理程序)

Step to be taken if material is released or spilled (物品溢出或泄露处理步骤):

Wasted Disposal Method(废弃物处理方式):

According to the general waste treatment.

依照普通废弃物处理。

Maybe gathered and returned to specified stations

应被收集和回收到特定地点: No (×)

Individual notice (单独标示):

Disposable use

一次性使用

SECTION VI Safety Disposition & Store Method (安全放置与储存方式)

Disposition (放置): Shady, dry, non-corrosiveness air environment(阴凉、干燥、无腐蚀性气体环境)

Respiratory Protection (呼吸保护措施): ----

Protective Gloves (保护手套): ----

Eye Protection (眼睛保护措施): ----

SECTION VII Physical Property (物理特性)

Weight(重量): ---

Rigidity (硬度): Soft (柔软)

Appearance (外观): Clean (透明, 干净)

SECTION VIII Stability & Reaction (稳定性与化学反应)

Stability: Stable (稳定性) Harm reaction (危险反应) Avoidance (避免)

稳定

No

Harmful of Decomposition (分解的危害性)

有毒氮氧化物和 CN-烟雾

SECTION IV Toxicity Information (毒性信息)

ROHS Toxicity 《电气、电子设备中限制使用某些有害物质指令》包括的毒性: Not sure (不确定)

Other Toxicity (其它毒性): Not sure (不确定)

SECTION VV Special Precaution (特殊预防)

Precaution to be taken in handling and storing (在处理与储存当中的预防)

Store in the shade to avoid exposure to the sun. 在阴凉处保藏, 避免暴晒。

Certificate CN15/20782

The management system of

Ningbo Chinmed Technology Co., Ltd.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design and Manufacture of the Non-sterile Wound Dressings, Sterile Wound Dressings, Sterile Medical Surgical Drapes, Sterile Hydrocolloid Dressings, Sterile Foam Dressings, Sterile Medical Tapes, Ostomy Bags, Alginate dressing, Silicon Gel Dressing, Hydrogel Dressing, Medical Bandages and Silicone Foam Dressings

This certificate is valid from 19 January 2024 until 18 January 2027 and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 18 January 2012

Jonathan M. Hall

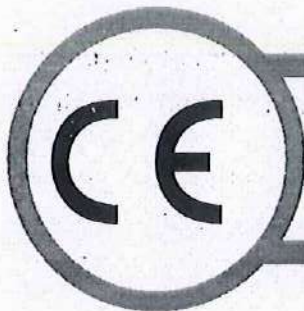
Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable Standards

EN ISO14971:2019
EN ISO15223-1:2021
EN ISO 20417: 2021
EN ISO10993-1:2020
EN ISO10993-5:2009
EN ISO10993-10:2013

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-M030403-02.*

*All the supporting documentation is retained at the
premises of the manufacturer.*

*The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.*

Manufacturer

Name: Ningbo Chinmed Technology Co., Ltd.
Address: No.20 Xingzhong Rd, Qijiashan street, Beilun
Area, Ningbo, Zhejiang Province, P.R.China
SRN: CN-MF-000023983

Product Information

Name: MEDICAL TAPE
Model: Customized
EMDN: M04010299
GMDN: 16866
Basic UDI-DI: 697286436300005A
Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Device
Regulation (EU) 2017/745 and the applicable
standards above.

Signature: 

Date: 2022.12.20

Position: GM

Place: Ningbo/China

