



## DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

**Manufacturer:**

Company name: Nanjing 3H Medical Products Co., Ltd.

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P.R. China

Tel:+86 02557885555

E-mail: [info@3hmedical.com](mailto:info@3hmedical.com)

SRN: CN-MF-000002303

**Whose Authorized Representative:**

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e  
Verd, 2595AA, The Hague,  
Netherlands. E-mail:

[peter@lotusnl.com](mailto:peter@lotusnl.com)

SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

<b>Product Name</b>	Kinesiology tape		
<b>Model</b>	See annex 01 Model		
<b>Intend use</b>	Mainly used for sports protection to reduce pain, improve circulation, reduce edema, promote healing, relax soft tissues, correct posture and revise incorrect action, and so on.		
<b>EMDN code</b>	M030403	<b>Basic UDI-DI</b>	See Annex 02 Basic UDI-DI
<b>Classification and rule</b>	I, rule I	<b>Conformity Assessment Route</b>	Article 19, Annex II and Annex III

**Applicable Standards and CS:**

EN ISO 13485:2016

EN ISO 14971:2019

ENISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2023

EN ISO 15223-1:2021

EN ISO 20417:2021

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process

Signed: *Mars*

Effective Date: May 6, 2024

Place: JiangSu, China

Version: C/8

Name of authorized signatory: Mars Jiang

Position held in the company: General Manager

Nanjing 3H Medical Products Co., Ltd.

Revised Date: 2024.05.06



## Annex 01 Model

### Rolled products:

12.5mm\*1.0m/2.0m/3.0m/3.4m/4.0m/4.5m/5.0m/5.4m/6.0m/7.5m/10m/12m/17m/25m/27m/30m/31.5m/32m/35m

25mm\*1.0m/2.0m/3.0m/3.4m/4.0m/4.5m/5.0m/5.4m/6.0m/7.5m/10m/12m/17m/25m/27m/30m/31.5m/32m/35m

38mm\*1.0m/2.0m/3.0m/3.4m/4.0m/4.5m/5.0m/5.4m/6.0m/7.5m/10m/12m/17m/25m/27m/30m/31.5m/32m/35m

50mm\*1.0m/2.0m/3.0m/3.4m/4.0m/4.5m/5.0m/5.4m/6.0m/7.5m/10m/12m/17m/25m/27m/30m/31.5m/32m/35m

75mm\*1.0m/2.0m/3.0m/3.4m/4.0m/4.5m/5.0m/5.4m/6.0m/7.5m/10m/12m/17m/25m/27m/30m/31.5m/32m/35m

100mm\*1.0m/2.0m/3.0m/3.4m/4.0m/4.5m/5.0m/5.4m/6.0m/7.5m/10m/12m/17m/25m/27m/30m/31.5m/32m/35m

### Flake products:

Model I:Length(50mm-400mm)\*Width(10mm\*350mm)

Model Y:Length(50mm-400mm)\*Width(10mm\*350mm)

Model X:Length(50mm-400mm)\*Width(10mm\*350mm)

Model W:Length(50mm-400mm)\*Width(10mm\*350mm)

Other Models:Length(50mm-400mm)\*Width(10mm\*350mm)




## Annex 02 Basic UDI-DI

Product Name	Product Code	Code	Basic UDI-DI
KineTape	MBJT	01	697402141MBJT01BZ
KineTape SY	RZSJT	01	697402141RZSJT012F
KineTape NY	NLJT	01	697402141NLJT01FU



## Product Information Sheet



REF/Code No.	SIZE	Produkt/ Product	Basic UDI-DI
522 541/0	5cmX 5m	DermaPlast Active, Kinesiologisches Tape – Pink ES,PT	697402141MBJT01BZ
522 442/0	5cmX 5m	DermaPlast Active, Kinesiologisches Tape- Beige DE,FR,NL,IT	
522 542/0	5cmX 5m	DermaPlast Active, Kinesiologisches Tape- Beige ES,PT	
522 642/0	5cmX 5m	Cosmos Active, Kinesiologisches Tape- Beige CZ,SK	
522 440/0	5cmX 5m	DermaPlast Active, Kinesiologisches Tape-Blau DE,FR,NL,IT	
522 540/0	5cmX 5m	DermaPlast Active, Kinesiologisches Tape-Blau ES,PT	
522 640/0	5cmX 5m	Cosmos Active, Kinesiologisches Tape- Blau CZ,SK	
522 441/0	5cmX 5m	DermaPlast Active, Kinesiologisches Tape- Pink DE,FR,NL,IT	
522 641/0	5cmX 5m	Cosmos Active, Kinesiologisches Tape- Pink CZ,SK	