

CE Technical File Declaration of conformity	Version: A/2
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EU Declaration of Conformity



Manufacturer:

Name: Nanjing 3H Medical Products Co.,Ltd.

Address: NO.1 and 5, ZhuShan Road, GaoChun Economic Development Zone.
NanJing, JiangSu Province, P.R.China

Tel: +86 02557885555

Whose Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

SRN:NL-AR-000000121

We, the manufacturer, herewith declare that the product(s)

Product Name	Cohesive Bandage	Adhesive Bandage	Tape	Plaster	Wrap	Kinesiology Tape
UMDNS_code	10288	10276	10030	16866	17604	10289
Models	Various size					
Classification	Class I , rule 1 of MDR Annex VIII					
Brand	3H					
BASIC UDI-DI	See annex I: Basic UDI DI list of product					
Intended Use	Cohesive Bandage 、 Adhesive Bandage 、 Tape 、 Plaster 、 Wrap : mainly used for sports protection, dressing fixation and joint protection. Nonsterile. Kinesiology Tape: 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. Nonsterile.					

Meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

SRN: CN-MF-000002303

We,the manufacturer,herewith declare under our sole responsibility that the medical device as specified above is in conformity with Regulation (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Mars Jiang

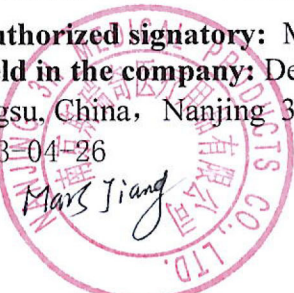
Position held in the company: Deputy General Manager

Place: Jiangsu, China, Nanjing 3H

Date: 2023-04-26

Signature:

Mars Jiang



annex I

Basic UDI DI list of product				
Name	Product Name	Product Code	Code	Basic UDI-DI
Kinesiology Tape	KineTape	MBJT	01	697402141MBJT01BZ
	KineTape-P	MBJT	02	697402141MBJT02C3
	KineTape SY	RZSJT	01	697402141RZSJT012F
	KineTape SY-P	RZSJT	02	697402141RZSJT022H
	KineTape NY	NLJT	01	697402141NLJT01FU
	KineTape NY-P	NLJT	02	697402141NLJT02FW
	KineTape BH	BHJT	01	697402141BHJT019L
Cohesive Bandage	FlexBand	FBZN	01	697402141FBZN01BQ
	FlexBand NR	FBZN	02	697402141FBZN02BS
	ComRip	KSZN	01	697402141KSZN01KL
	CoRip	MBZN	01	697402141MBZN01EK
	CoRip NR	MBZN	03	697402141MBZN03EP
	EcoRip	JJMBZN	01	697402141JJMBZN01ZP
	FlexGrip	JZMBZN	01	697402141JZMBZN01AA
	FlexGrip NR	JZMBZN	03	697402141JZMBZN03AE
	CoFix	ZWPBT	01	697402141ZWPBT012P
	CoFix NR	ZWPBT	03	697402141ZWPBT032T
	CoGau	PWPBT	01	697402141PWPBT01VA
	CoGau NR	PWPBT	03	697402141PWPBT03VE
	CoFoam	HMZN	01	697402141HMZN01GB
	CoFoam NR	HMZN	03	697402141HMZN03GF
	Super Flex	SMKSZN2	01	697402141SMKSZN201VZ
	Super Flex NR	SMKSZN2	03	697402141SMKSZN203W5
	Pro Flex	SMKSZN3	01	697402141SMKSZN301W6
	Pro Flex NR	SMKSZN3	03	697402141SMKSZN303WA
	PowerPad	QRZN	01	697402141QRZN01MP
	PowerPad H	BRZN	01	697402141BRZN01FL



Tape	RegTape	PBYD	01	697402141PBYD01DZ
	PorTape	PBYD	02	697402141PBYD02E3
	SerTape	CBYD	01	697402141CBYD018Q
	SorTape	CBYD	02	697402141CBYD028S
	ColTape S	CSCBYD	01	697402141CSCBYD01UG
	ColTape	CSPBYD	01	697402141CSPBYD01ZR
	Cross Tape	SZJD	01	697402141SZJD01L7
	Pepore S	LGPE	01	697402141LGPE01CA
	Pepore M	YGPE	01	697402141YGPE01HK
	Pepore P	GDPE	01	697402141GDPE0198
	Ecopore	WFZJD	02	697402141WFZJD02UU
	Ecopore P	WFZJD	01	697402141WFZJD01US
	Nonwpore	WFBJD	01	697402141WFBJD01LJ
	Foam Tape	PMJD	01	697402141PMJD01EH
	Silkpore EC	SCJD	02	697402141SCJD02CC
	Silkpore	SCJD	01	697402141SCJD01CA
	Silkpore P	GDSCJD	01	697402141GDSCJD01SF
	Light Fix EC	FLJ	02	697402141FLJ029X
	Light Fix	FLJ	01	697402141FLJ019V
	Soft Derm	WFBFLT	01	697402141WFBFLT0126
Adhesive Bandage	Elasti Plus HM	KOB	01	697402141KOB01AZ
	Elasto Tape EA	QSB	01	697402141QSB01DX
	Elasto Tape	DTMB	01	697402141DTMB01CD
	LightWrap	KSMB	01	697402141KSMB01EV
	LightRip	KSMB	03	697402141KSMB03EZ
	Elasto Plus HM	YMN	01	697402141YMN01H9
	Elasto Plus ZO	YMN	02	697402141YMN02HB
Wrap	Under wrap	HMCD	01	697402141HMCD019Q
	Wrap	WNBD	01	697402141WNBD01FX
Plaster	Locker Tape	RZMYHX	01	697402141RZMYHX01LK
	Micro Plaster ZOP	MBYHX	02	697402141MBYHX02Q9

