

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Hangzhou Yoniner Pharmaceutical Co., Ltd**
No.42, Yangcheng Road, Nanyang Street, Xiaoshan
District, Hangzhou, Zhejiang 311227 P.R. China

SRN **Not available yet**

EC Authorized Representative: **MedPath GmbH**
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN **DE-AR-000000087**

We, the manufacturer, declare under our sole responsibility that

Trademark:

Yoniner 永宁尔

Trade name:

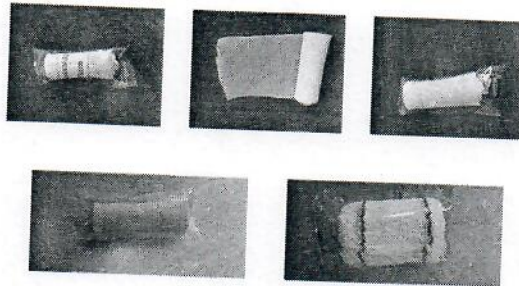
Bandages

the medical device:

Bandages

Product photograph

Specification: See Annex 1



Applied Standard & Common Specification:

EN ISO 13485:2016 / EN ISO 14971: 2019
ISO10993-1:2018 / EN ISO10993-5:2009
EN ISO 10993-10:2013 / EN ISO 15223-1:2016
694019389700J2

Basic UDI-DI:

Class I, Rule 1

of class:

N.A.

CE certificate No.:

N.A.

Name and ID of the Notified Body:

according to annex VIII of Regulation EU 2017/745(MDR)

Meets the provisions of the Regulation EU 2017/745(MDR). The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

Annex II, Annex III of EU 2017/745

Zhejiang /2021-06-04

Feiye LI/ General Manager

Zhejiang / 2021-06-04

Feiye LI / General Manager

Place, date /

Name and function

Annex 1: Dimensions Bandages (Unit: mm)

Size	Wide	Allowable error	Stretch length	Allowable error	Size	Wide	Allowable error	Stretch length	Allowable error
5x130	5	≥95%	130	≥95%	5x360	5	≥95%	360	≥95%
6x130	6				6x360	6			
7.5x130	7.5				7.5x360	7.5			
8x130	8				8x360	8			
10x130	10				10x360	10			
15x130	15				15x360	15			
20x130	20				20x360	20			
5x200	5	≥95%	200	≥95%	5x4Y	5	≥95%	4Y	≥95%
6x200	6				6x4Y	6			
7.5x200	7.5				7.5x4Y	7.5			
8x200	8				8x4Y	8			
10x200	10				10x4Y	10			
15x200	15				15x4Y	15			
20x200	20				20x4Y	20			
5x230	5	≥95%	230	≥95%	5x4.1Y	5	≥95%	4.1Y	≥95%
6x230	6				6x4.1Y	6			
7.5x230	7.5				7.5x4.1Y	7.5			
8x230	8				8x4.1Y	8			
10x230	10				10x4.1Y	10			
15x230	15				15x4.1Y	15			
20x230	20				20x4.1Y	20			
5x250	5	≥95%	250	≥95%	5x375	5	≥95%	375	≥95%
6x250	6				6x375	6			
7.5x250	7.5				7.5x375	7.5			
8x250	8				8x375	8			
10x250	10				10x375	10			
15x250	15				15x375	15			
20x250	20				20x375	20			
5x270	5	≥95%	270	≥95%	5x400	5	≥95%	360	≥95%
6x270	6				6x400	6			
7.5x270	7.5				7.5x400	7.5			
8x270	8				8x400	8			
10x270	10				10x400	10			
15x270	15				12x400	12			
20x270	20				15x400	15			
5x300	5	≥95%	300	≥95%	20x400	20	≥95%	450 4Y	≥95% ≥95%
6x300	6				5x450	5			
7.5x300	7.5				6x450	6			
8x300	8				7.5x450	7.5			
10x300	10				8x450	8			
15x300	15				10x450	10			
20x300	20				15x450	15			
					20x450	20			
					5x5Y	5	≥95%	5Y	≥95%
					6x5Y	6			
					7.5x5Y	7.5			
					8x5Y	8			
					10x5Y	10			
					15x5Y	15			
					20x5Y	20			

Remarks: Under the premise that the production process, product composition, and performance indicators of the company's products remain unchanged, the size of the product is adjusted according to market demand.