

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**
SRN **Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany**
DE-AR-000000087

We, the manufacturer, declare under our sole responsibility that

Trademark:

YONINER 永宁尔

Trade name:

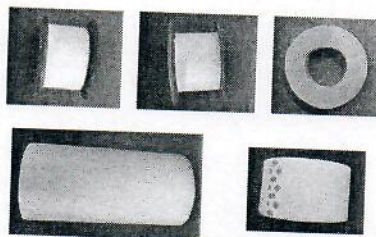
Medical Tapes

the medical device:

Medical Tapes

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
694019389300HE

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 Medical Tapes (Unit: mm)

No.	Wide	High	No.	Wide	High	No.	Wide	High	No.	Wide	High	No.	Wide	High
1	1	450	11	1	500	21	1	800	31	1	914	41	1	1000
2	1.25	450	12	1.25	500	22	1.25	800	32	1.25	914	42	1.25	1000
3	2.5	450	13	2.5	500	23	2.5	800	33	2.5	914	43	2.5	1000
4	3.8	450	14	3.8	500	24	3.8	800	34	3.8	914	44	3.8	1000
5	5	450	15	5	500	25	5	800	35	5	914	45	5	1000
6	7.5	450	16	7.5	500	26	7.5	800	36	7.5	914	46	7.5	1000
7	10	450	17	10	500	27	10	800	37	10	914	47	10	1000
8	15	450	18	15	500	28	15	800	38	15	914	48	15	1000
9	20	450	19	20	500	29	20	800	39	20	914	49	20	1000
10	26	450	20	26	500	30	26	800	40	26	914	50	26	1000

Remarks: Under the condition that the product raw materials, structure composition, performance, and scope of application are unchanged, the size is customized according to customer requirements.