

Doc. No.	YM/CE 84-01C	Ver.	C	Page code	1/1
Document Name	Declaration of Conformity	Effective Date	2021-06-01		

Declaration of Conformity

Manufacturer

Name: Ningbo Yingmed Medical Instruments Co.,Ltd.

Address: Room1201-9,Yingsheng building,No.456 Tai'an RD, Southern business Zone, Yinzhou district, Ningbo, China

Tel.: +86-574-89065797

Fax: +86-574-89065812

SRN: CN-MF-000002183

European Representative:

Name: Lotus NL B.V.

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

Email: peter@lotusnl.com

SRN: NL-AR-000000121

MEDICAL DEVICE:

Model Name: Spacer for Aerosol

Type or size: Body volume(175ml, 198ml); mask size(S,M,L); Model(YM-A039, YM-A038, KI-200)

Basic UDI-DI: 697458075A039GU

GMDN : 38018

Classification: Class I, according to rule I, Annex VIII, Regulation(EU)2017/745

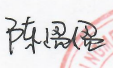
Conformity Assessment Procedure: Annex II+Annex III of MDR

We herewith declare in our own responsibility that the above-mentioned product(s) according to Art.19 of Regulation(EU) 2017/745 on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Applicable standard(s): EN ISO13485:2016/ EN ISO 14971:2019/ ISO 15223-1:2016/ EN 1041:2008+A1:2013/ EN10993-1:2018/ EN ISO 10993-5:2009/ EN ISO 10993-10:2013/ ISO 10993-12:2021/ EN ISO 5356-1:2015/ EN 62366-1:2015/ ISO18562-1:2017

Notified Body: N.A.

CE Certificate No.: N.A.

Signature: 



Date of Issue:2021-06-01

Name: Chenyingying

Position: General Manage

Place: Room1201-9,Yingsheng building,No.456 Tai'an RD, Southern business Zone, Yinzhou district, Ningbo, China