

EC Declaration of Conformity



Manufacturers Name:



Jiangmen Xinli Medical Apparatus and Instruments Co., Ltd

Manufacturers Address:

The 3rd floor, Building 2, NO.7 Tongfa Road, Gaoxin
District, Jiangmen City, Guangdong Province, China 529000
CN-MF-000024032

SRN (Single Registration Number):

Authorized Representative Name (if applicable):



Authorized Representative Address (if applicable):

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Basic UDI-DI:

Not available yet

Name of the Device (s):

Cupping device (negative pressure Cup)

Model/Specification

JM-030-BL
JM-030-BL-4T
JM-030-BL-6T
JM-030-BL-8T
JM-030-BL-14T

JM-030-BL-X
JM-030-BL-X1
JM-030-BL-X2
JM-030-BL-X3
JM-030-BL-X4
JM-030-BL-X5
JM-030-BL-X6

JM-030-PP
JM-030-PP-A
JM-030-PP-B
JM-030-PP-C
JM-030-PP-D
JM-030-PP-E
JM-030-PP-F

JM-030-PC
JM-030-PC-4T
JM-030-PC-6T
JM-030-PC-8T
JM-030-PC-10T
JM-030-PC-12T
JM-030-PC-13T
JM-030-PC-17T
JM-030-PC-18T
JM-030-PC-19T
JM-030-PC-23T
JM-030-PC-24T
JM-030-PC-25T
JM-030-PC-30T

JM-030-PC-X1
JM-030-PC-X2
JM-030-PC-X3
JM-030-PC-X9
JM-030-PC-X10

JM-030-SC
JM-030-SC-3T
JM-030-SC-4T
JM-030-SC-5T
JM-030-SC-12T
JM-030-SC-1
JM-030-SC-2
JM-030-SC-3
JM-030-SC-4
JM-030-SC-5

MDR 2017/745; ENISO13485:2016; ENISO15223-1:2021;
EN1041:2008+A1:2013; ENISO14971:2019

Standards:

Classification:

Class I, Rule 1

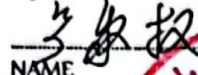
Conformity assessment route:

Jiangmen Xinli Medical Apparatus and Instruments Co.,
Ltd uses the following procedures for the CE-labeling of
their products according the Regulation MDR 2017/745:

Class I: EC conformity declaration according to annex
VIII

This declaration of conformity is issued under the sole responsibility of Jiangmen Xinli Medical Apparatus and
Instruments Co., Ltd, We hereby declare that the medical device(s) specified above meet the provision of the
Regulation (EU) MDR 2017/745 for medical devices.
All supporting documentation is retained at the premises of the manufacturer.

Signature:



NAME

FUNCTION CEO



Place and date (dd.mm.yyyy) of issue:

May 20, 2022
Jiangmen, China