

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Shenzhen Coralrich Technology Co.,Ltd.
Building A,B,C,Yuanfen Industrial Zone B,Taoyuan
Community,Dalang Street,Shenzhen,China

Trademark: N.A.

SRN: Not available yet

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: **Nasal Wash**

Product Name: **Nasal Wash**

Model: CR-7100,CR-7101,CR-7102,CR-7101
ZY-XBQ-V ,ZY-XBQ-VI,ZY-XBQ-VII ,ZY-XBQ-VIII ,
ZY-XBQ-IX,ZY-XBQ-X,ZY-XBQ-XI,ZY-XBQ-XII,
ZY-XBQ-XIII,ZY-XBQ-XIV,ZY-XBQ-XV,ZY-XBQ-XVI,
ZY-XBQ-XVII,ZY-XBQ-XVIII,ZY-XBQ-XIX,ZY-XBQ-XX

Basic UDI: N.A.

Classification acc. to MDR Ax. VIII: Class I, rule I

Applied Standard & Common Specification: EN ISO 14971:2012

Conformity assessment procedure: Annex II + Annex III of MDR

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), and the provision of the Regulation (EU) 2016/425 on personal protective equipment. All supporting documentations are retained under the premises of the manufacturer.



Qianzheng Hong,
General Manager

Wenzhou, 31. 01. 2021