



EU DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo 18, CP29006,
Málaga-Spain

SRN: ES-AR-000000293

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection
with the release technical document
CE/MDR-Q030199-01.

All the supporting documentation is retained at the
premises of the manufacturer.

The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.

Manufacturer

Name: Guangzhou Daoke Biomedical Technology Co.,
Ltd.

Address: 25# Room 203, No.90-96(Even
Number) Science Avenue, Huangpu District, Guangzhou
City, Guangdong Province, China

Product Information

Name : Nasal Irrigator

Model : DKNC01, DKNC02, DKNC03, DKNC04

EMDN : Q030199

Basic UDI-DI : 697622930 830 M5

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Intended Use: The Nasal Irrigator is intended to
dispense a solution to clear and clean the nasal
passages and sinus cavity for the relief of nasal and
sinus symptoms. the device is reuse and provided
non-sterile.

Declaration

We, the manufacturer, herewith declare under our
sole responsibility that above-mentioned products
meet the provisions of the Regulation (EU) 2017/745
on medical (MDR). All supporting documentations are
retained under the premises of the manufacturer

Signature: Paul Huang

Date: 2023-03-01

Position:  Place: Guangzhou/China