DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	Beijing Rongrui-Century Science&Technology Co., Ltd 3 rd Floor, West zone, No.1Building, No.7Yard, Fengxian middle Road, Haidian District, Beijing100094, P.R, China
MEDICAL DEVICE:	NASAL CANNULA
MODEL:	RVL001S, RVL001M and RVL001L
CLASSIFICATION - ANNEX IX:	CLASS Ⅱ A, RULE 2 ACCORDING TO ANNEX IX OF THE MDD
CONFORMITY ASSESSMENT ROUTE:	ANNEX II EXCLUDING SECTION 4

WE, BEIJING RONGRUI-CENTURY SCIENCE&TECHNOLOGY CO., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.
STANDARDS APPLIED: *APPLIED EU HARMONIZED STANDARDS.*

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	NO. G1 067381 0014 VALID UNTIL: DEC. 1ST, 2023

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
DIMDI NO.: DE/0000040627

START OF CE-MARKING: JAN. 2020

PLACE, DATE OF DECLARATION: CITY: BEIJING, DATE: APR. 10TH 2021

SIGNATURE:

NAME: CHANG HAN
POSITION: MANAGEMENT REPRESENTATIVE