



DECLARATION OF CONFORMITY

CONCERNING MEDICAL DEVICE DIRECTIVE 93/42/EEC

MANUFACTURER:	SHENZHEN REALTONE MEDICAL APPLIANCE CO.,LTD. FLAT B, 5 FLOOR, YAOXIANG INDUSTRIAL BULIDING, NO.92 FUKANG ROAD, HENGGANG STREET, LONGGANG DISTRICT, SHENZHEN, CHINA.
PRODUCT:	DISPOSABLE MEDICAL MASK(NON-STERILE)
MODEL:	CM2006, CM2008
RELEVANT EC DIRECTIVE:	MEDICAL DEVICE 93/42/EEC(MDD)
CLASSIFICATION:	CLASS I ACCORDING TO ANNEX IX OF DIRECTIVE 93/42/EEC
UMDN CODE:	15-230
CONFORMITY ASSESSMENT PROCEDURE:	EC DECLARATION OF CONFORMITY (MEDICAL DEVICE 93/42/EEC(MDD))

WE, SHENZHEN REALTONE MEDICAL APPLIANCE CO.,LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, AND THE ESSENTIAL REQUIREMENTS OF ANNEX VII OF THE DIRECTIVE 93/42/EEC. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

APPLIED NORMATIVE DOCUMENTS:	EN 14683:2019
REGISTRATION NUMBER:	DE/CA20/01-LUXUSLEBENSWELT-504/20
EUROPEAN REPRESENTATIVE:	LUXUS LEBENSWELT GMBH KOCHSTR.1,47877,WILLICH,GERMANY

PLACE, DATE OF DECLARATION: SHENZHEN, MAY.21, 2020
Yingchao Xie
NAME: YINGCHAO XIE
POSITION: MANAGEMENT REPRESENTATIVE

