European Commission

DECLARATION OF CONFORMITY

MANUFACTURER: SHENZHEN MERRILL TECHNOLOGY CO. , LTD

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EU AUTHORISED REPRESENTATIVE: LUXUS LEBENSWELT GMBH (EUROPE)
ADDRESS: KOCHSTR 1.47877.WILLICH.GERMANY
DIMDI CODE: DE/0000047791

DEVICE: MERRILL DISPOSABLE FACE MASK
MEDL NO: MERRILL KM95-001
TYPE: TYPE IIR ; FACT TYPE DECLARATION
SIZE: 17.5CM×9.5CM
CLASSIFICATION(93/42/ECC ANNEX IX RULES 1): CLASS I
CONFORMITY ASSESSMENT ROUTE: ANNEX VII

WE,SHENZHEN MERRILL TECHNOLOGY CO.,LTD,HEREWITH DECLARE ON OUR EXCLUSIVI REPONSIBILITY THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AND 2007/47/EC FOR MEDICAL DEVICES AS TRANSPOSED INTO NATIONAL LAW.All SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARD APPLIED:

STANDARDS	STANDARD'S TITLE
ISO 13485:2016	MEDICAL DEVICE - QUALITY MANAGEMENT SYSTEMS - REQUIREMENT FOR REGULATORY PURPOSES
EN ISO 14971:2019	MEDICAL DEVICES - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
EN ISO15223-1:2016	MEDICAL DEVICES - SYMBOLS TO BE USED WITH MEDICAL DEVICE IABLES, LABELLINGAND INFORMATION TO BE SUPPLIES- PART 1 GENERAL REQUIREMENTS
EN 1041:2008	INFORMATION SUPPLIED BY THE MANUFACTURER OF MEDICAL DEVCES
MEDDEV 2.7.1:REV4	EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACHURERS AND NOTIFIED BODIES
EN 14683:2019	MEDICAL FACE MASKS - REQUIREMENTS AND TEST METHODS
EN ISO 10993-1:2009	BIOLOGICAL EVALUATION OF MEDICAL DEVICES -- PART 1 :EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
EN ISO 10993-5:2009	BIOLOGCAL EVALUATION OF MEDICAL DEVICES -- PART 5: TEST FOR IN VITRO CYTOTOXICITY.
EN ISO10993-10:2013	BIOLOGCAL EVALUATION OF MEDICAL DEVICES -- PART 10:TESTS FOR INITATION AND SKIN SENSITIZATION

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CE

SIGNATURE:

MR.SAM CHENG
POSITION: GERNERAL MANAGER