## **DECLARATION OF CONFORMITY** TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



MANUFACTURER:

WEIGAO MEDICAL INTERNATIONAL CO., LTD.

No.1, WEIGAO ROAD, HIGH-TECH INDUSTRIAL

DEVELOPMENT ZONE, 264210, WEIHAI, SHANDONG PROVINCE, PEOPLE'S REPUBLIC OF

CHINA

MEDICAL DEVICE:

MEDICAL FACE MASK

UMDNS CODE: 12458

TYPE AND / OR MODEL: TYPE: WGP-A WGP-B

CLASSIFICATION - ANNEX IX:

CLASS I.RULE 1

CONFORMITY ASSESSMENT ROUTE: ANNEX VII

TRADE MARK: WEMED

WE, WEIGAO MEDICAL INTERNATIONAL 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 MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE

(EC) CERTIFICATE(S):

N/A

EC REP

EUROPEAN REPRESENTATIVE:

MEDNET EC-REP GMBH(EUROPE)

BORKSTRASSE 10 • 48163 MUENSTER • GERMANY

START OF CE-MARKING:

N/A

PLACE, DATE OF DECLARATION:

WEIHAI. 2020-03-17

SIGNATURE:

NAME: SONGXINLAN

POSITION: (Management Representative)