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

MANUFACTURER: *GUANGDONG YUEHUA MEDICAL INSTRUMENT FACTORY CO.,LTD*
RONGSHENG SCIENCE AND TECHNOLOGY ZONE, DAXUE ROAD,
SHANTOU, GUANGDONG,
CHINA

PRODUCT NAME: *ALTERNATING PRESSURE MATTRESS*
MODEL: *QDC-300,QDC-301,QDC-303,QDC-500,QDC-501,QDC-800*
QDC-501B

CLASSIFICATION - *ANNEX IX*: *CLASS I, RULE12*

CONFORMITY ASSESSMENT ROUTE: *ANNEX VII + V.3*

WE, THE MANUFACTURER, 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 APRIL 2011, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN 60601-1:1990+A1:1993+A2:1995
EN 60601-1-2:2007
EN ISO 13485:2012 / AC:2012
EN ISO 14971:2007
EN 980:2008
EN 1041:2008

EC REP
EUROPEAN REPRESENTATIVE: *WELLKANG LTD T/A WELLKANG TECH CONSULTING*
SUITE B, 29 HARLEY STREET
LONDON W1G 9QR, ENGLAND, UNITED KINGDOM

START OF CE-MARKING: *2014-10-10*

PLACE, DATE OF DECLARATION: *SHANTOU, 2014-10-10*

SIGNATURE: SuJue

NAME:SUJUE
POSITION: GENERAL MANAGER

GUANGDONG YUEHUA MEDICAL INSTRUMENT FACTORY CO.,LTD. 广东粤华医疗器械厂有限公司

Digitally signed by Potînga Stela
Date: 2019.12.09 09:07:01 EET
Reason: MoldSign Signature
Location: Moldova