

**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, RULE 12*

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*

