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

MANUFACTURER: *XIAMEN SENYANG CO LTD*
ADD: 4-5 FLOOR,XINGBEI INDUSTRY,NO 95-99，WEST 2 ROAD,JIU TIANHU,XINGLIN,XIAMEN,361000，CHINA

MEDICAL DEVICE: *ALTERNATING PRESSURE MATTRESS WITH PUMP*
*MODEL: APP-P05(B01);APP-P05(T01C)*

CLASSIFICATION : *CLASS1 ANNEX VII*

*CONFORMITY ASSESSMENT ROUTE:* *93/42EEC*

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 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 13485:2012; EN60601-1：2006/IEC60601-1：2005;EN 60601-1-2:2007

*IDENTIFICATION NUMBER* CE

(EC) CERTIFICATE(S): *EC CERTIFICATE(S) NUMBER(S)*

EC REP

EUROPEAN REPRESENTATIVE:

DROMOS EUROPE S.L.
SAN FRANCISCO, 44-1º
48003 BILBAO – VIZCAYA – SPAIN.
in European Union

START OF CE-MARKING: 2016.02

PLACE, DATE OF DECLARATION: *XIAMEN ,CHINA 2016.3.31*

SIGNATURE: 王平

厦门森洋工贸有限公司 单证章 XIAMEN SENYANG CO.,LTD

*NAME: WANG PING*