

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

MANUFACTURER: SHENZHEN LIFOTRONIC TECHNOLOGY Co.,LTD
UNIT A, 4TH FLOOR, BUILDING 15, YIJING ESTATE, No.1008 SONGBAI ROAD, NANSHAN
DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, 518055, P.R.CHINA

MEDICAL DEVICE: AIR COMPRESSION THERAPY SYSTEM

MODEL: *AIRPRO-300,AIRPRO-600,PRESSCARE G200M,PRESSCARE G300M, G300M,
G200M,AIRPRO-660,AIRPRO-680,AIRPRO- 690,AIRPRO-360,AIRPRO-380,
AIRPRO-390*

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 9

CONFORMITY ASSESSMENT ROUTE: ANNEX II

WE, SHENZHEN LIFOTRONIC TECHNOLOGY 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.

AND are in conformity with the national standards transposing harmonised standards:

AIRPRO-300,AIRPRO-600,PRESSCARE G200M,PRESSCARE G300M:

EN ISO 13485: 2016	EN ISO 14971: 2012	EN 1041:2008+A1:2013
EN ISO 15223-1:2016	EN 62304:2006+A1:2015	EN 60601-1-6:2010+A1:2015
EN 62366:2008+A1:2015	EN 60601-1:2006+A1:2013	EN 60601-1-2:2015
ISO 10993-5:2009	ISO 10993-10:2010	

*G300M,G200M,AIRPRO-660,AIRPRO-680,AIRPRO- 690,AIRPRO-360,AIRPRO-380,
AIRPRO-390:*

EN ISO 13485: 2016	EN ISO 14971: 2012	EN 1041:2008+A1:2013
EN ISO 15223-1:2016	EN 980:2008	EN 62304:2006+A1:2015
EN 60601-1-6:2010+A1:2015	EN 62366:2008+A1:2015	EN ISO 10993-1:2009/AC: 2010
EN ISO 10993-5:2009	EN ISO 10993-10:2010	EN 60601-1:2006+A1:2013
EN 60601-1-2:2015	EN 60601-1-11:2015	

NOTIFIED BODY: SGS FIMKO Ltd.

IDENTIFICATION NUMBER: 0598

(EC) CERTIFICATE(S): FI20/07001

EUROPEAN REPRESENTATIVE: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH
(EUROPE)

EIFFESTRASSE 80, 20537 HAMBURG, GERMANY
TEL: +49-40-2513175 FAX: +49-40-255726

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CONCERNING MEDICAL DEVICES**

PLACE, DATE OF DECLARATION: CHINA, GUANGDONG PROVINCE, 2022.04.20

SIGNATURE:



NAME: LEI XIANG 项磊

POSITION: *MANAGEMENT REPRESENTATIVE*