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

MANUFACTURER:	*ZERO-PLUS INTERNATIONAL LTD.* *ROOM 1004, 10/F, JOIN-IN HANG SING CENTRE,* *71-75 CONTAINER PORT ROAD,* *KWAI CHUNG, NEW TERRITORIES, HONG KONG*
MEDICAL DEVICE:	*VENENWALKER PRO2 TURQUOISE, CUFF SHORT* *002-1008-22, 002-1008-23* *VENENWALKER PRO2 TURQUOISE, EXTENSION SHORT* *002-1008-20* *VENENWALKER PRO2 TURQUOISE, ARM-CUFF* *002-1008-15, 002-1008-16* *VENENWALKER PRO2 TURQUOISE, CUFF* *002-1008-12, 002-1008-13* *VENENWALKER PRO2 TURQUOISE, EXTENSION* *002-1008-10*
CLASSIFICATION - *ANNEX IX*:	*CLASS I, RULE 1*
UMDNS CODE:	*11072*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX VII*

WE, ZERO-PLUS INTERNATIONAL 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 THIS DOC

STANDARDS:	BIOCOMPATIBILITY - ISO 10993-1:2018
CE	
EC REP EUROPEAN REPRESENTATIVE:	GLOBALMIND CONSUMER ELECTRONICS GMBH ERNST-MANTIUS-STR.11 21029 HAMBURG, GERMANY
START OF CE-MARKING:	*2019-11-01*
PLACE, DATE OF DECLARATION:	HONG KONG, *2021-01-07*
SIGNATURE:	_____ *NAME: ESTHER LAU* *POSITION: MANAGEMENT REPRESENTATIVE*