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 BASIC RED, LEG EXTENSION* *003-1009-27* *VENENWALKER BASIC RED, CUFF* *003-1009-25, 003-1009-26* *VENENWALKER BASIC TURQUOISE, LEG EXTENSION* *002-1009-27* *VENENWALKER BASIC TURQUOISE, CUFF* *002-1009-25, 002-1009-26*
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