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

MANUFACTURER:	*ZERO-PLUS INTERNATIONAL LTD.*
MEDICAL DEVICE:	*L.E.D. MINI DAYLIGHT – MDLEDV1, MDLEDV2, MDLEDV3, MDLEDV4, MDLEDV5, MDLEDV6*
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 9*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II EXCLUDING (4)*

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. THIS DECLARATION OF CONFORMITY IS ISSUED UNDER OUR SOLE RESPONSIBILITY.

STANDARDS APPLIED:	ENISO 13485:2012/AC :2012 IEC 60601-1:2005/A 1 :2012 EN 60601-1-2:2015 IEC 60601-1-11 :2015 IEC 60601-2-57 :2011 EN ISO 14971:2012 EN 1041:2008 + A1 :2013 EN ISO 15223-1 :2016
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	G1 16 01 70522 012
EC REP EUROPEAN REPRESENTATIVE:	I-PLUS COMPANY LIMITED 4B CHRISTCHURCH HOUSE, BEAUFORT COURT, MEDWAY CITY ESTATE, ROCHESTER, KENT. ME2 4FZ

START OF CE-MARKING:	2018-01-19 *VALID UNTIL: 2020-03-19*

PLACE, DATE OF DECLARATION:	HONG KONG, *2018-01-19*
SIGNATURE:	*NAME: PETER LAU* *POSITION: PROJECT MANAGER*