

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:

L.E.D. MINI DAYLIGHT – MDLEDV1, MDLEDV2,
MDLEDV3, MDLEDV4, MDLEDV5, MDLEDV6

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 9

UMDNS CODE:

15228

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. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THIS DoC

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

G1 070522 0014 REV. 01

VALID UNTIL:

2024-05-26



EUROPEAN REPRESENTATIVE:

GLOBALMIND CONSUMER ELECTRONICS GMBH
ERNST-MANTIUS-STR.11
21029 HAMBURG, GERMANY

START OF CE-MARKING:

2017-08-01

PLACE, DATE OF DECLARATION:

HONG KONG, 2024-03-25

SIGNATURE:


NAME: ESTHER LAU
POSITION: GENERAL MANAGER