

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



MANUFACTURER:

NAME: SOLARIS MEDICAL TECHNOLOGY, INC
ADDRESS: ZHONGJIAN INDUSTRIAL BUILDING ONE, #401,
18 YANSHAN ROAD, SHEKOU, NANSHAN DISTRICT,
518067 SHENZHEN, GUANGDONG,
PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:

SPO₂ ADAPTING CABLES

PRODUCT SERIES:

AC011 SERIES: AC011-015, AC011-025, AC011-028, AC011-030, AC011-101, AC011-050103X,
AC011-105, AC011-110, AC011-116, AC011-163, AC011-177, AC011-177-1,
AC011-177-2, AC011-182, AC011-182-1, AC011-182-2, AC011-182(1)-11,
AC011-183-4, AC011-200183-6, AC011-183(1), AC011-183(1)D,
AC011-183(1)-2, AC011-183(1)-5, AC011-183(1)-8, AC011-184, AC011-110-1,
AC011-115, AC011-033, AC011-183G-21

AC022 SERIES: AC022-011, AC022-046, AC022-061A, AC022-119

AC031 SERIES: AC031-025, AC031-025-2, AC031-025-2X, AC031-025-3M, AC031-027M,
AC031-029X, AC031-031, AC031-046, AC031-050, AC031-061, AC031-061-1MA,
AC031-061-3, AC031-061-4X, AC031-061-5X, AC031-061-4A, AC031-072M,
AC031-073M, AC031-074, AC031-074-1, AC031-075, AC031-075X, AC031-087,
AC031-087-1, AC031-088, AC031-110, AC031-113, AC031-113-2X, AC031-115X,
AC031-122, AC031-122-1, AC031-122-1X, AC031-131, AC031-131-1, AC031-177,
AC031-178, AC031-180, AC031-182, AC031-182-1, AC031-182(3)-1,
AC031-183X, AC031-183-5, AC031-183-13, AC031-183-23, AC031-183(1),
AC031-183(1)M, AC031-183(1)-1, AC031-183(1)-2, AC031-183(1)-8,
AC031-183(1)-10, AC031-183(2)M-3, AC031-183(2)-4, AC031-184, AC031-185,
AC031-330185-1, AC031-183G-15, AC031-183(3)G-21X, AC031-183-15,
AC031-184-2, AC031-184-2x, AC031-025-4, AC031-028, AC031-100131

AC032 SERIES: AC032-025, AC032-061, AC032-074, AC032-075, AC032-075X, AC032-087,
AC032-114, AC032-183(1)G-14, AC032-183(3)-21, AC032-183(3)G-21X

AC033 SERIES: AC033-042, AC033-046, AC033-061B, AC033-131-1, AC033-131-2

AC034 SERIES: AC034-164

AC035 SERIES: AC035-061-1, AC035-073, AC035-100108, AC035-179-1, AC035-183(2)

AC036 SERIES: AC036-027, AC036-061A, AC036-073, AC036-088

AC051 SERIES: AC051-011, AC051-061-2, AC051-119

AC061 SERIES: AC061-023, AC061-121

AC071 SERIES: AC071-025, AC071-025-1, AC071-025-2, AC071-087

AC081 SERIES: AC081-131-1, AC081-183(1)

AC185 SERIES: M106-AC185 (2)

GROUP/UMDNS: 11493—ELECTROSURGICAL UNIT ADAPTERS, CABLE

CLASSIFICATION:

CLASS I,

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

WE, SOLARIS MEDICAL TECHNOLOGY, INC., 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.

STANDARDS APPLIED: EN 60601-1:2006/A1:2013, EN 60601-1-2:2007,
ISO 80601-2-61:2011, EN ISO 10993-1:2009, EN ISO 14155-2011, EN ISO 15223-1-2012,
EN 1041:2008, EN980:2008

IDENTIFICATION NUMBER



PLACE, DATE OF DECLARATION:

SHENZHEN, JUNE. 6, 2018

AUTHORIZED SIGNATURE:

wei zheng