EU DECLARATION OF CONFORMITY
MEDICAL DEVICE REGULATION 2017/745

MANUFACTURER:

COMPANY NAME:	SOLARIS MEDICAL TECHNOLOGY, INC.
COMPANY ADDRESS :	ZHONGJIAN INDUSTRIAL BUILDING ONE #401, 18 YANSHAN ROAD, SHEKOU NANSHAN DISTRICT 518067 SHENZHEN, GUANGDONG PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000038492
MEDICAL DEVICE:	SpO2 ADAPTING CABLES
PRODUCT MODEL:	SEE ATTACHMENT 1
GROUP/ UMDNS:	11493—ELECTROSURGICAL UNIT ADAPTERS, CABLE
BASIC UDI-DI:	6900234AC001FW
INTENDED PURPOSE:	THE CABLE IS INTENDED TO CONNECT SpO2 SENSORS TO PATIENT MONITORS
CLASSIFICATION :	CLASS I , RULE 1
CONFORMITY ASSESSMENT ROUTE:	MEDICAL DEVICE REGULATION 2017/745 ANNEX II&III, IV

WE, SOLARIS MEDICAL TECHNOLOGY, INC., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES THAT IS COVERED BY THE PRESENT DECLARATION IS IN CONFORMITY WITH MEDICAL DEVICE REGULATION 2017/745

THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.

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STANDARDS APPLIED:

EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, ISO 80601-2-61:2017, EN ISO 15223-1-2021, EN ISO 20417:2021

EC REP

EUROPEAN AUTHORIZED REPRESENTATIVE:

COMPANY NAME: Shanghai International Holding Corp. GmbH (Europe)

COMPANY ADDRESS: Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

PLACE, DATE OF DECLARATION: SHEN ZHEN, OCT 15, 2025

SIGNATURE: Chunhui Xu

NAME: CHUNHUI XU

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)

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MEDICAL DEVICE REGULATION 2017/745

ATTACHMENT 1—MODEL LIST

DEVICE TYPE	MODEL NO.
SPO2 ADAPTING CABLES	**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

EU DECLARATION OF CONFORMITY
MEDICAL DEVICE REGULATION 2017/745

	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)