

**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

SHEZHEN, GUANGDONG , PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:

PRODUCT NAME: MULTI-COMPATIBLE SpO_2 SENSORS

PRODUCT MODEL: SEE ATTACHED LIST

GROUP / UMDNS: 37808—REUSABLE OXIMETER PROBES

31658—SINGAL USE OXIMETER PROBES

CLASSIFICATION – ANNEX IX:

CLASS IIb, RULE 10 ACCORDING TO ANNEX IX OF THE MDD

CONFORMITY ASSESSMENT ROUTE:

COUNCIL DIRECTIVE 93/42/EEC (MDD), ANNEX II, ITEM 3.

We, SOLARIS MEDICAL TECHNOLOGY, INC., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 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: SEE ATTACHED LIST OF (HARMONISED-EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH

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RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S) :

No. G1 065690 0016 Rev. 00

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING:

2019-5-13

PLACE, DATE OF DECLARATION:

SHEN ZHEN, MAY 13, 2019

SIGNATURE:

NAME: Zheng Wei

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)

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LIST OF (HARMONISED-EN) STANDARDS

FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED



NO.	Standard Name	Reference NO.
1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	EN60601-1:2006/A1:2013
2	Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use	ISO 80601-2-61:2011
3	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	EN ISO10993-5:2009
4	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	EN ISO10993-10:2010
5	Clinical investigation of medical devices for human subjects-good Clinical Practice(ISO14155:2011)	EN ISO14155:2011
6	Information supplied by the manufacturer of medical devices	EN 1041:2018+A1:2013
7	Medical devices –Part 1:Application of usability engineering to medical devices	EN 62366-1:2015
8	Symbols for use in the labelling of medical devices	EN 980:2008

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Models of D Series

(Multi-compatible Disposable SpO2 Sensors For Single Patient Multiple Use)

D100P, D100A, D100AL, D100AXL Models (Total 4):

D200P, D200A, D200AL, D200AXL Models (Total 4):

D300P, D300A, D300AL, D300AXL Models (Total 4):

D400P, D400A, D400AL, D400AXL Models (Total 4):

Models of DP Series

(Multi-compatible Disposable SpO2 Sensors For Single Patient One Use)

DP100I, DP100P, DP100A, DP100N/A, DP100N Models (Total 5):

DP200I, DP200P, DP200A, DP200N/A, DP200N Models (Total 5):

DP300I, DP300P, DP300A, DP300N/A, DP300N Models (Total 5):

DP400I, DP400P, DP400A, DP400N/A, DP400N Models (Total 5):



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Models of T Series

(Multi-compatible Reusable SpO2 Sensors For Soft-Finger)

T100P, T100A, T100AL Models (Total 3) :

T200P, T200A, T200AL Models (Total 3) :

T300P, T300A, T300AL Models (Total 3) :

T400P, T400A, T400AL Models (Total 3) :

Models of S Series

(Multi-compatible Reusable SpO2 Sensors For Finger)

S100A, S100P Models (Total 2) :

S200A, S200P Models (Total 2) :

S300A, S300P Models (Total 2) :

S400A, S400P Models (Total 2) :

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Models of W Series

(Multi-compatible Reusable SpO2 Sensors For Wrap)

W100A/N, W100P/I Models (Total 2) :

W200A/N, W200P/I Models (Total 2) :

W300A/N, W300P/I Models (Total 2) :

W400A/N, W400P/I Models (Total 2) :

Models of Y Series

(Multi-compatible Reusable SpO2 Sensors For Y Type)

Y100 Models (Total 1) :

Y200 Models (Total 1) :

Y300 Models (Total 1) :

Y400 Models (Total 1) :

