DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:	Shenzhen Caremed Medical Technology Co., Ltd. East side, 3/F, C Building, Kelunte Low-carbon industrial park, Gaofeng Community, Dalang office, Longhua district, 518109/ Shenzhen PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Probes, Oximeter (Gmdns code 17594) SpO2 sensor
CLASSIFICATION - *ANNEX IX*:	*CLASS IIB, RULE10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II.3*

WE, THE MANUFACTURER, 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:	*SEE ATTACHED LIST 1*
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	G1 088955 0007 Rev.01

EC REP

EUROPEAN REPRESENTATIVE:
SUNGO EUROPE B.V.
ADD: OLYMPISCH STADION 24, 1076DE AMSTERDAM

START OF CE-MARKING: *2015/2/10*

PLACE, DATE OF DECLARATION: Shenzhen, 2023-1-31

SIGNATURE: Alan Xie

PRINT *NAME: ALAN XIE*
POSITION: QUALITY MANAGER

Annex to Declaration of Conformity

Spo2 sensor, P/N:

SA11E-06
SA30Y-75
SA30Y-23
SA30S-23
SA30E-23
SA30E-09
130010468
SA11E-127
SA36Y-02
SA11Y-127
SA11E-117
SA30E-121
SA30E-09
SA11Y-117
SA40Y-121
SA30Y-09
SA11S-117
SA30S-121
SA20Y-21M
SA20E-121
SA30Y-60
SA20E-60
SA11Y-01
SA11E-01
SA30E-01
SA11M-01
SA05F-01
SP05F-01
SI09F-01
SN09T-01
SN09F-01
SAN11W-01
SN09N-01
SA15Y-16
SP15S-16
SA15E-16
SP11S-08
SP30S-80L
SA30S-08
SA30Y-20
SA15S-91

SA30S-91
SA11S-01
SI11S-01
SN11W-91
SN11W-01
SA15E-91
SA30E-91
SA15Y-91
SA30Y-91