



BIOMETRIC CABLES

Excellence till Acceptance

(ISO 13485:2016 Certified Facility)

EC DECLARATION OF CONFORMITY FOR CLASS IIb
Medical Device– Cirus Oxygen Sensor
Biometric Cables

A - 28, Phase - 3, SIDCO Industrial Estate, Guindy, Chennai -600 032, Tamil Nadu, India

Phone: +91-44-22500953/54/56/57. Email: info@biometriccables.com

URL: www.biometriccables.com

I, Biometric cables, hereby declare under our sole responsibility that the medical devices specified below:

Product Name: **Cirus Oxygen Sensor (910245005)**

Authorized Representative: CMC Medical Devices & Drugs S.L.C/ Horacio Lengo N° 18,
 CP29006, Málaga-Spain. Tel: +34951214054

info@cmcmedicaldevices.com

Standard	Title
EN ISO 13485:2012	Medical Devices – Quality Management Systems – Requirements for regulatory purposes
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN1041:2008+A1:2013	Information supplied by the Manufacturer of Medical Devices
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 80601-2-55:2011	Particular requirements for the basic safety and essential performance of respiratory gas monitors
IEC 60601-1:2005+AMD1:2012	Medical electrical equipment – General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Conforms to the Essential Requirements listed in Annex I of EC Directive 93/42/EEC as amended by EC Directive 2007/47/EC and Restriction of the use of Hazardous Substances Directive (RoHS 2), 2011/65/EU.

This declaration is made under AnnexII excluding point 4 conformity assessment route of EC Directive 93/42/EEC, concerning medical devices issued by Notified Body,

Notified Body Name: POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.(PCBC)

Address: ul. Klobucka 23A, 02-692 Warszawa, Country: Poland

Phone: +48 (22) 4645201

Fax: +48 (22) 6471222

Email: polskie.centrum@pcbc.gov.pl

Website: www.pcbc.gov.pl

Signed

Date ..08-06-2021..

C.ARUNKUMAR

Chief Executive Officer(On behalf of Biometric Cables)



A. K. GUPTA
 DIRECTOR (COMMERCIAL)
 GLOBAL EXPORTS CHAMBER OF COMMERCE
 R. No. C1202 Date

02 JUL 2021



www.biometriccables.in

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