

**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: +91-44-22500953/54/55/57. Email: [info@biometriccables.com](mailto:info@biometriccables.com)URL: [www.biometriccables.com](http://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@cmcmmedicaldevices.com](mailto:info@cmcmmedicaldevices.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, 02-693 Warszawa, Country: Poland**Phone: **+48 (22) 4645201**Fax: **+48 (22) 6471222**Email: **[polskie.centrum@pcbc.gov.pl](mailto:polskie.centrum@pcbc.gov.pl)**Website: **[www.pcbc.gov.pl](http://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. **C/202** Date**02 JUL 2021**

Corporate Office:

A28, Phase 3, SIDCO Industrial Estate, Guindy

Chennai - 600 032, Tamil Nadu, India

Tel: +91 44 2250 0953/54/56/57

Email: [info@biometriccables.com](mailto:info@biometriccables.com)

Branch Office:

Plot No.13, Phase-3, SIDCO Industrial Estate

Valavanthankottai, Tiruchirapalli - 620 015

Tel: +91 93810 24426, 94437 29410

Email: [info@biometriccables.com](mailto:info@biometriccables.com)[www.biometriccables.in](http://www.biometriccables.in)