

**BIOMETRIC CABLES***Excellence till Acceptance*

(ISO 13485:2016 Certified Facility)

EC DECLARATION OF CONFORMITY FOR CLASS I**Medical Device– Cirus Flow sensor****Biometric Cables**

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

Product Name: Flow sensor-1, Flow sensor-2 and Flow sensor-3

Authorized Representative: CMC Medical Devices & Drugs S.L.C/ Horacio Lengo N° 18,

CP29006, Málaga- Spain.Tel: +34951214054.

Email: info@cmcmedicaldevices.com

Standard	Title
ISO 13485:2016	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
EN 1041:2008+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 5356-1:2015	Anaesthetic and respiratory Equipment-Conical connectors-Part 1: Cones and Sockets
ISO 10993-1:2018	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 Annex II excluding point 4 conformity assessment route of EC Directive 93/42/EEC, concerning medical devices issued by Notified Body,

Signed

Date24-09-2021.....

C.ARUNKUMAR**Chief Executive Officer (On behalf of Biometric Cables)**

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