

CERTIFICATE OF COMPLIANCE

No: CE -1902

Certificate
Holder

BIOMETRIC CABLES

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

Product(s)

Cirus Flow Sensor

Part number(s)

910246001, 910246002, 910246003

Verification to:

Standard:
 EN ISO 13485:2016, EN ISO 14971:2012,
 EN ISO 15223-1:2016, EN 1041:2008,
 ISO 10993-1:2018, ISO 10993-5:2009,
 ISO 10993-10:2010, IEC 62366-1:2015,
 ISO 5356-1:2015, EN ISO 80601-2-12:2011,
 EN ISO 80601-2-13:2012

Related to Directive:
 93/42/EEC + 2007/47/EC (Medical Devices)
 Class I (rule 1)
 As per Annex VII

Issue date 27 JULY 2020

Expiry date 26 JULY 2022

Remark: Based on the successful review of technical construction file documentation of the above mentioned products, UCAS confirms manufacturer ability to keep permanently the required safety and quality level. The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this certificate. The certificate remains valid until the manufacturing conditions and quality system as per the technical documentation are maintained or relevant legislation are changed. The product liability rests with the manufacturer or his representative in accordance with applicable Directive and Standard, after fulfilling the relevant EU legislation requirements, the manufacturer shall affix CE mark to each medical device of the above reference models.



Authorised Signatory

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