CREATE BIOTECH CO., LTD.
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Declaration of Conformity

Manufacturer:
Name: Create Biotech Co., Ltd.
Address: 6F-12, No. 9, Sec. 2, Nankan Rd., Luzhu Dist., Taoyuan City 338, Taiwan
E-mail: info@create-biotech.com

European Authorized Representative:
Name: JouMed Technology OÜ
Address: Sepapaja 6, Tallinn 15551, Estonia
E-mail: joumed.tech@create-biotech.com

We, the manufacturer, hereby declare that the below mentioned devices have been classified and complied with the essential requirements of the harmonized directives, regulatory and standards.

- Device name: Breathing Circuit and Accessories
- Device series code /or model no.: 001 series, 002 series, 003 series, 004 series, 009 series, 010 series, 013 series, 014 series, 016 series, and 017 series.
- Classification: Class IIa, Rule 2 of Annex IX of the Directive 93/42/EEC
- Conformity Assessment Procedure:
  Annex V of the Directive 93/42/EEC (Production Quality Assurance)
- Harmonized Standards:
  - EN ISO 13485:2016, Medical devices. Quality management systems. Requirements for regulatory purposes.
  - EN ISO 14971:2012, Medical devices. Application of risk management to medical devices
  - 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 ISO 8835-2:2007, Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems.
  - EN 12342:1998+A1:2009, Breathing tubes intended for use with anaesthetic apparatus and ventilators.
  - EN ISO 5356-1:2015, Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets.
  - EN ISO 5367, Anesthetic and Respiratory Equipment – Breathing sets and connectors.
  - EN ISO 18190:2016, Anesthetic and Respiratory Equipment – General Requirements for airways and related equipment.
  - EN ISO 594-1:1986, Conical Fittings with a 6% (Luer) taper for syringes ,needles and certain other medical equipment –Part 1: General Requirements.

This declaration of conformity is valid from: 1/Dec/2017 until any specifications change.

Authorized Signatory:

Johnson Huang

President

1/Dec/2017

Date

Digitally signed by Prodan Sveatoslav
Date: 2022.05.30 15:30:11 EEST
Reason: MoldSign Signature
Location: Moldova