BLACKFROG TECHNOLOGIES PRIVATE LIMITED

D.NO:3-72(E), KORGI VILLAGE, HOSMATA POST, KUNDAPUR – 576231, KARNATAKA, INDIA CIN: U28133KA2015PTC083851



An ISO 13485:2016 certified Medical Devices Company

Ref No: BFT/DND/2022-2023-001

DECLARATION OF CONFORMITY

The declaration of conformity is issued under the sole responsibility of the manufacture

Issuer

Business name: Blackfrog Technologies

Private Limited

Address: 3-72E, PHR Shetty Building,

Korgi, Hosmata, Kundapura, Udupi,

Karnataka, 576231

Additional address:

1. No 4, 4th floor, Centre for Advance Research, Behind MMMC, Madhav Nagar,

Udupi, Karnataka, 576104

2. Dr TMA Pai Polytechnic College, OLD PRINTING LAB BUILDING, GROUND

FLOOR, TMA PAI POLYTECHNIC, Eshwar Nagar, Udupi, Udupi, Karnataka,

576104

Country: India

Product

Name: Emvolio Model: Pro/Plus

Description: Transportable, powered

vaccine storage appliances

Product photo



We declare that the product described above, to which this declaration of conformity refers to, conforms with the essential requirements of the following EU legislation:

- MDR 2017/745 for medical devices as per Article 19 for class 1.

Through the technical standards/specifications specified below:

 IEC 60601-1-2:2014+A1:2020/ EN 60601-1-2:2015 (EMC/EMI and electrical safety) under group 1 for class 1 devices.

- The risk class of the device is classified under Class I Rule 1.

The declaration is supported by the Quality System Approval to ISO 13485:2016 issued by MTIC InterCert India Pvt. Ltd.

Signed by 27th May, 2022 Udupi, India Mr. Mayur U Shetty
Chief Executive Officer
Blackfrog Technologies Private Limited