



Reference no: BFT/QAD/2025-2026/008

18 Sep 2025

Version:02

DECLARATION OF CONFORMITY

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

Issuer

Business name: Blackfrog Technologies Private Limited

Address: D No. 16-329 B-11, 3rd Floor,
RSB Bhavan, Manipal-Alevoor Road,
Opp MJC, Manipal-576104

Additional address:

Manufacturing Unit-1
8-148I(1), Ground Floor,
Old Printing Lab, Inside Dr. T.M.A Paj Polytechnic Campus,
Eshwara Nagar, Manipal,
Karnataka, India - 576104.

Country: India

Product

Name: Emvolio

Model: Pro/Plus

Description: A Portable temperature
regulated carrier for transport of biologicals

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** certificate no. 87 102 001 18058, issued by TÜV Rheinland (India) Pvt. Ltd.

Signed by

18th September 2025

Udupi, India


Mr. Mayur U Shetty
Chief Executive Officer
Blackfrog Technologies Private Limited