



EC DECLARATION OF CONFORMITY

Manufacturer:

Name: GyroGear Pte Ltd.

Address: Block 67 Ayer Rajah Crescent #04-23/24, Singapore 139950

Authorized Representative in the European Union:

- **Name:** Jack Dove
- **Email ID:** jack@gyrogear.co
- **Address:** 90A High Street, Berkhamsted, Hertfordshire, HP4 2BL, United Kingdom

Product:

- **Product Name:** GyroGlove
- **Model size :** Extra-Large, Large, Medium, Small size for left /Right hand
- **Product Description:** ANTI-TREMOR GYROSCOPIC ORTHOTIC GLOVE

Classification:

- **Device Classification:** Wearable Medical Device
- **Risk Class:** Class 1

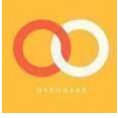
Conformity Assessment Procedure:

- **Procedure Followed:**
ISO 13485 : 2016

Notified Body:

- **Name:** SGS United Kingdom Ltd
- **Ref. Cert. Number:** SG24/00000015
- **Address:** Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK


Standards Applied:



- ISO 13485:2016.
- EN ISO 14971:2012
- IEC 60601:2014

Declaration:

We, GyroGear Ltd., hereby declare under our responsibility that the product mentioned above meets the provisions of the Council Directive 98/79/EC concerning Class 1 wearable medical devices. This declaration is supported by the Quality Management System as per ISO 13485:2016 and the conformity assessment procedure of IEC 60601:2014.

Signature: 



Craig Smith , Head of Regulatory
Date: 03 June 2024

Attachments:

1. **Annex A:** ISO 13485:2016 Certificate
2. **Annex B:** CB Certificate