Under sole responsibility, the undersigned hereby certify that the medical device(s) described hereinafter as:

**Product Name/Designation:** Invacare Perfecto2 Series Oxygen Concentrators

**Model(s)/Code(s):** IRC5PO2VAW

**GMDN Code(s):** 31321

with the following locations:

- **Manufacturer:** Invacare Corporation
  - **Address:** 2101 E. Lake Mary Blvd.
  - **City, State, Province:** Sanford, Florida 32773
  - **Country:** United States of America

- **EU Representative:** Invacare Deutschland GmbH
  - **Address:** Kleiststrasse 49, D-32457
  - **City, State, Province:** Porta Westfalica
  - **Country:** Deutschland

is (are) in conformity with;

- **Medical Device Directive 93/42/EEC - Annex VII, as classification IIa, using Annex IX - Rule 11,**

Article 4 of the RoHS Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 for restriction of the use of certain hazardous substances in electrical and electronic equipment,

the following harmonized standard(s),

- IEC 60601-1 Issued: 2012/08/20 ED 3.1
- IEC 62366:2007 Ed.1
- EN ISO 13485:2012
- BS EN 15223-1:2012
- EN 62366:2015


**Engineering Representative**

- **Name:** William Daniels
- **Signature:** [Signature]
- **Date:** 11/4/17

**Site Quality Representative**

- **Name:** Jeff Manno
- **Signature:** [Signature]
- **Date:** 11/4/17

**Regulatory Affairs Representative**

- **Name:** Elijah Wreh
- **Signature:** [Signature]
- **Date:** 14-Nov-17