CE Declaration of Conformity / Déclaration CE de Conformité

(MDD)

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

Product Name/Designation: Invacare Perfecto2 Series Oxygen Concentrators

Model(s)/Code(s): IRC9LXO2AWQ, IRC5PO2VAW
GMDN Code: 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),
EN ISO 13485:2012
EN ISO 14971:2012
EN ISO 15001:2011
BS EN 15223-1:2012
EN 1041:2008
EN 55011:2009/A1:2010
EN 60601-1:2006/AC 2010
EN 61000-3-2:2006 A1:2009. A2:2009
Rn 61000-3-3:2008
EN 60601-1-8: 2012
EN 62366:2015
and using a quality management system certified to ISO 13485: 2003 by SGS United Kingdom Ltd., Systems and Certification, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, U.K, Certificate Number: US97/10267,

Medical Device Directive 93/42/EEC monitoring and supervision by SGS United Kingdom Ltd., 202B Worle Parkway, Weston-super-Mare, BS22 6WK, U.K., as Notified Body 0120, Certificate Number: US11/82188.

Signed by: _____ Date: 19 JUNE 2017 On behalf of: Invacare Corp.
Name: Joseph Kuebler Title: Engineering Manager

Signed by: _____ Date: June 20, 2017 On behalf of: Invacare Corp.
Name: Jeff Manno Title: Site Quality Manager

Signed by: _____ Date: 20-Jun-17 On behalf of: Invacare Corp.
Name: Elijah Wreh Title: Regulatory Affairs Manager