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 Solo2 Transportable Oxygen Concentrators
Model(s)/Code(s): TPO100, TPO100B

with the following locations;

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

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

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 1041:2008
EN ISO 13485:2012
EN ISO 14971:2012
BS EN ISO 15223-1:2012
EN ISO 8359:2009, AMD 1:2012
EN 60601-1:1990:, A1:1993, A2:1995
EN 60601-1-2:2007
EN 61000-3-2:2006
EN 61000-3-3:2008

and using a quality management system certified to ISO 13485: 2003 by SGS United Kingdom Ltd., Systems and Services Certification,, Certificate Number: US97/10267,

with Medical Device Directive 93/42/EEC monitoring and supervision by SGS United Kingdom Ltd., as Notified Body 0120 , Certificate Number: US11/82188 to Annex V.

Signed by: _____ Date: Dec. 5, 2014 On behalf of: Invacare Corp.
Name: Douglas Uelmen Title: SVP QA RA

Signed by: _____ Date: 12/15/2014 On behalf of: Invacare Corp
Name: Jeffrey Manno Title: Quality Manager

Signed by: _____ Date: _____ On behalf of: _____
Name: _____ Title: _____