



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: Kleiststrasse 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 8359-2:2009, 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: US97710267,

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: [Signature] Date: Dec 5, 2014 On behalf of: Invacare Corp.
Name: Dariusz Ulewien Title: SVP QA RA

Signed by: [Signature] Date: 12/15/2014 On behalf of: INVACARE Corp
Name: Jeffrey Mann Title: Quality Manager

Signed by: [Signature] Date: 1/18/2015 On behalf of: INVACARE Europe
Name: Andros Papanou Title: Dir. of Quality + Regulatory Affairs EU