



# 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),

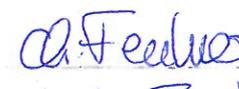
- EN 1041:2008
- EN ISO 13485:2012
- EN ISO 14971:2012
- BS EN ISO 15223-1:2012
- EN ISO 8359:2009, AMD 1:2012
- EN 60601-1:1990, A1:1993, A2:1995
- EN 60601-1-2:2007
- EN 61000-3-2:2006
- EN 61000-3-3:1995, A1:2001, A2:2005

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: 9/17/2014 On behalf of: Invacare Corp  
Name: Douglas Deimen Title: SVP QARA

Signed by:  Date: 9/19/2014 On behalf of: INVACARE CORP  
Name: JEFFREY MANNO Title: QUALITY MANAGER

Signed by:  Date: 09/26/2014 On behalf of: IVC Europe  
Name: Christoph Feulner Title: Compliance Manager