

EC Declaration of Conformity

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

EU Representative:

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

Declares that the medical device(s) described hereafter

Product Name: Solo2 Transportable Oxygen Concentrator Models: TPO100, TPO100B

Having a classification of <u>IIa</u> using Annex IX rule <u>11</u> is (are) in conformity with the essential requirements and provisions of Council Directive 93/42/EEC, per Annex VII, is (are) in conformance with the following standard(s):

EN 980:2008 EN 1041:2008 EN ISO 8359:2009 EN ISO 13485:2003/AC:2009 EN ISO 14971:2009 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 is (are) designed and manufactured under a quality management system, certified to ISO 13485:2003 by SGS United Kingdom Ltd., Systems and Services Certification, Certificate Number: US97/10267

I, the undersigned, hereby declare that the device specified above conforms to Directive 93/42/EEC

416,22,2012 Signature Date

Name: Auto-As UECMEN Title: Sr VP QA/RA On behalf of:

Signature

Name: JEFFREY MANNO Title: QA MANAGER On behalf of:

FM04019c

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