

EC Declaration of Conformity

Manufacturer:

Invacare Corporation

EU Representative:

Invacare Deutschland Gmbl-

Invacare

Address:

2101 Lake Mary Blvd.

Address:

Kleiststrasse 49, D-32457

City, State, Province:

Sanford, Florida 32773

City, State, Province:

Porta Westfalica

Country:

United States of America

Country:

Germany

Declares that the medical device(s) described hereafter

Product Name: XPO2 Portable Oxygen Concentrator

Models: XPO100, XPO100B

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 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

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Name: LOUG-AS LIEUMEN

Date

Title:

Sr. UP QA/RA

On behalf of:

Signature

mature — 1

Title: CA MANAGES

On behalf of:

FM04019c

Rev. Date: 8/31/09

Effectivity Date: 9/1/09