EC Declaration of Conformity

Invacare Corporation
2101 Lake Mary Blvd
Sanford, Florida 32773
United States of America

Invacare International Sarl
Route de Cité Ouest 2
1196 Gland
Switzerland

Declares that the medical device(s) described hereafter

Invacare XPO2 Concentrators
Model: XPO100, XP0100B

having a classification of IIa using Annex IX Classification Criteria, Rule 11, is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as required by Annex VII, and is in conformity with the following national standard(s)

ISO 13485:2003
ISO 14971:2000
EN 980:2003
ISO 7000:2004
EN 1041:1998
IEC 60601-1: 1995
IEC 60601-1-2: edition 2.1
IEC 61000-3-2: 2005
IEC 61000-3-3: 2005
EN 60601-1-2 2nd edition
EN 61000-3-2: 2000
EN 61000-3.3: 1995

And per Annex II, is designed and manufactured under a quality management system, certified to ISO 13485:2003 by SGS United Kingdom Ltd., Systems and Services Certification, Certificate Number: 0120.

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

Quality Manager

Signature, <Title>

Name: Gerry Finley
Title: Quality Manager
On behalf of: Invacare Corporation