

EC Declaration of Conformity

Manufacturer: Address: Invacare Corporation 2101 Lake Mary Blvd EU Representative: Address: Invacare International Sarl Route de Cité Ouest 2

City, State, Province: Country: Sanford, Florida 32773 United States of America City, State, Province: Country: 1196 Gland Switzerland

Declares that the medical device(s) described hereafter

Product Name: SOLO2 Models: TP0100, TP0100B

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/EFC, per Annex VII, is (are) in conformance with the following standard(s):

ISO 14971: 2007 IEC 60601-1: 1988

with Amendment 1: 1991 and Amendment 2: 1995

ISO 8359: 1996
ISO 13485: 2003
IEC 60068-2-29 (Eb)
IEC 60068-2-36 (Fc)
IEC 60601-1-2: 2.1 edition
IEC 61000-3-2: 2005

IEC 61000-3-3: 2005 EN 61000-3-2: 2005 CISPR 11: 2007 EN 1041: 1998 EN 980: 2008

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: US03/3024

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

Signature

Name: Gerry Finley
Title: Quality Manager

On behalf of Invacare Corporation

Name: Carroll Martin

Title: Regulatory Affairs Manager On behalf of Invacare Corporation

FM04019c

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