SGS

Mr. Jeffrey Manno
Invacare Corporation
2101 E. Lake Mary Blvd.
Sanford, FL 32773

WW/PCI/07875
7 September 2012

Dear Mr. Manno:

Following the recent re-appraisal of your Company's Management System, I am pleased to inform you that the System in operation conforms to the requirements of MDD 93/42/EEC Annex II (excluding Section 4); MDD 93/42/EEC Annex V; CMDR; and ISO 13485:2003.

In line with our policy of continuous registration, the certificate now shows the date of original registration, the current issue date and number, and the expiry date of the certificate.

Enclosed are copies of your Certificates. Duplicate copies of these can be purchased by contacting me.

Yours sincerely,

Laura Prioli

Laura Prioli
Health Care/Medical Device Specialist
laura.prioli@sgs.com

EC Certificate Full Quality Assurance System: Certificate US98/12047

The management system of

Invacare Corporation

2101 E. Lake Mary Blvd.,
Sanford, FL, 32773, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Oxygen cylinders with regulators. Pediatric flow meter.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 16 September 2012 until 16 September 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 September 2015
Issue 13. Certified since 17 December 1998

Certification is based on reports numbered WW/PCI 07875

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311

EC Certificate Production Quality Assurance System: Certificate
US11/82188

The management system of

Invacare Corporation

2101 E. Lake Mary Blvd.,
Sanford, FL, 32773, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Oxygen concentrator systems.

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 16 September 2012 until 16 September 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 September 2015
Issue 2. Certified since 17 December 1998

Certification is based on reports numbered WW/PCI 07875

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311

Certificate US03/3024

The management system of

Invacare Corporation

2101 E. Lake Mary Blvd.,
Sanford, FL, 32773, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

Manufacture of hospital beds, hand-held oxygen analyzers, home medical equipment, such as oxygen concentrators. Design and manufacture of oxygen conservation devices.

Effective Date 21 November 2012 Expiry Date 21 November 2015
Re certification audit due before 15 September 2015
Valid subject to satisfactory surveillance audits.
Issue 10. Certified since 1 October 2003

Authorised by
Jan Saunders – Business Manager

SCC Accredited
CB-MS
OCSM
Accrédité CCN
TM

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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CMDCAS recognised registrar

SGS 13485 CMDCAS 0311

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Certificate US97/10267

The management system of

Invacare Corporation

2101 E. Lake Mary Blvd.,
Sanford, FL, 32773, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2003 / AC:2009

For the following activities

Design and manufacture of oxygen cylinders with regulators. Manufacture of hospital beds, air mattresses, home medical equipment, such as oxygen concentrators.

This certificate is valid from 16 September 2012 until 16 September 2015
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 September 2015
Issue 12. Certified since 30 June 1997

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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SGS 13485-2 0911

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