



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,

A handwritten signature in black ink that reads 'Laura Prioli'.

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

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

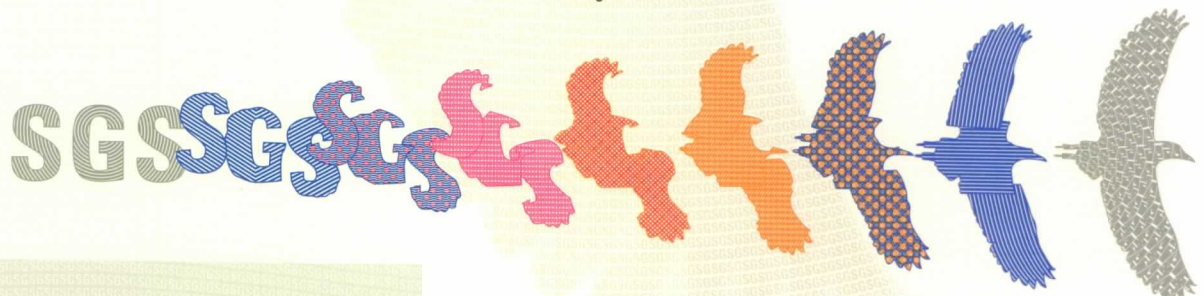
Authorised by

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

Page 1 of 1



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

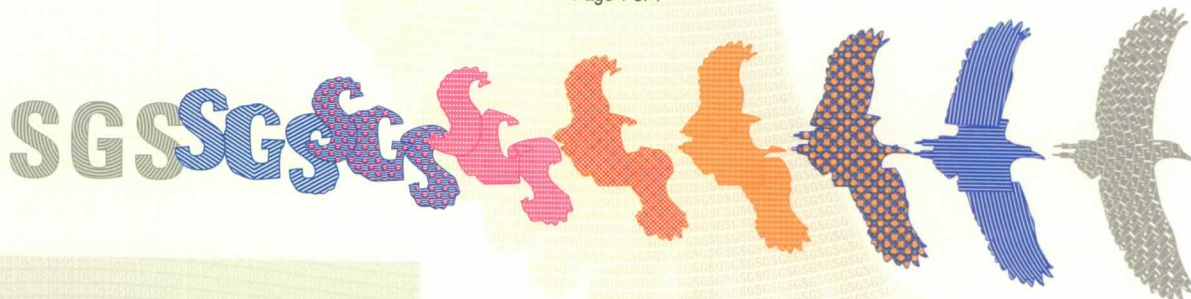
Authorised by

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

Page 1 of 1



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.**

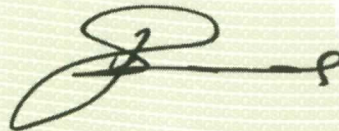
Effective Date 21 November 2012 Expiry Date 21 November 2015

Re certification audit due before 15 September 2015

Valid subject to satisfactory surveillance audits.

Issue 10. Certified since 1 October 2003

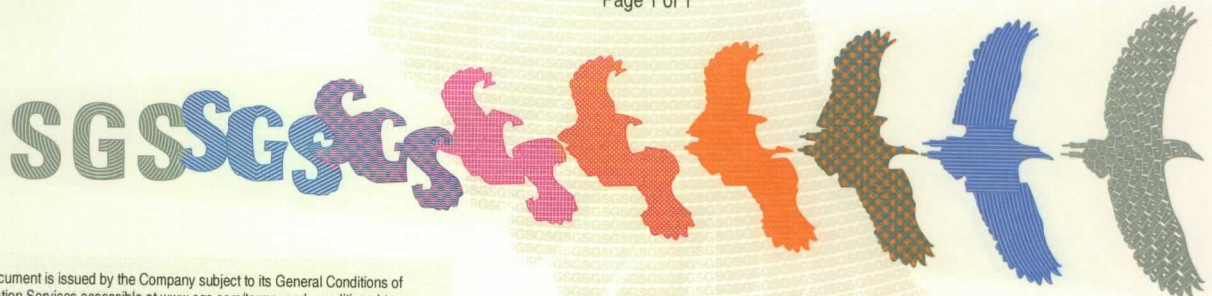
Authorised by  
Jan Saunders – Business Manager



SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)  
CMDCAS recognised registrar

SGS 13485 CMDCAS 0311

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at [http://www.sgs.com/clients/certified\\_clients.htm](http://www.sgs.com/clients/certified_clients.htm). Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

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

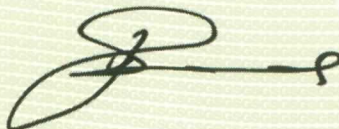
### ISO 13485:2003 EN ISO 13485:2003 / AC:2009

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



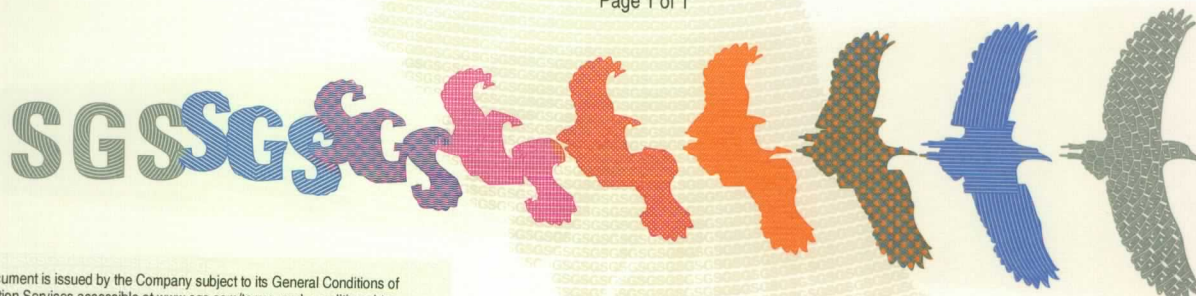
SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t+44 (0)151 350-6666 f+44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0911

Page 1 of 1



005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at [http://www.sgs.com/clients/certified\\_clients.htm](http://www.sgs.com/clients/certified_clients.htm). Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.