EC Certificate Full Quality Assurance System: Certificate US19/819943503



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

Cylinders with regulators, nasal masks, and pediatric flow meters for oxygen therapy

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 01 December 2019 until 15 September 2023 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 17 December 1998 and first certified by SGS Belgium on 01 December 2019.

Certification is based on reports numbered WW/MC 07875

Authorised by

Pieter Weterings Certification Manager

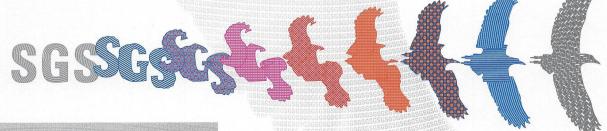
SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

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EC Certificate Production Quality Assurance System: Certificate US19/819943504



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 covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 01 December 2019 until 15 September 2023 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 17 December 1998 and first certified by SGS Belgium on 01 December 2019.

Certification is based on reports numbered WW/MC/ 07875

Authorised by

Pieter Weterings Certification Manager

SGS Belgium NV, Notified Body 1639

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