Yes, you can.

CE Declaration of Conformity / Déclaration CE de Conformité
(MDD)

Under sole responsibility, the undersigned hereby certify that the medical device(s) described hereinafter as;

Product Name/Designation: Invacare® Perfecto$_2$ V Oxygen Concentrator

Model(s)/Code(s): IRC5PO2VAW

GMDN Code(s): 31321

with the following locations;

Manufacturer Invacare Corporation
Address: 2101 E. Lake Mary Blvd.
City, State, Province: Sanford, Florida 32773
Country: United States of America

EU Representative: Invacare Deutschland GmbH
Address: Kleiststraße 49, D-32457
City, State, Province: Porta Westfalica
Country: Deutschland

is (are) in conformity with;

Medical Device Directive 93/42/EEC - Annex V_ as classification IIa _ using Annex IX - Rule 11_,

Article 4 of the RoHS Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 for restriction of the use of certain hazardous substances in electrical and electronic equipment,

the following harmonized standard(s),

EN 1041:2008	ISO 10993-10:2010	ISO 15001:2010	IEC 60601-1-2: 2014	IEC 62304:2006
ISO 10993-1:2009	ISO 10993-11:2010	ISO 15223-1:2016	EN 60601-1-6:2010	IEC 62366-1:2015
ISO 10993-5:2009	EN ISO 14971:2012	EN 60601-1:2006/A1:2013	EN ISO 80601-2-69:2014	

and using a quality management system certified to ISO 13485: 2016 by SGS United Kingdom Ltd., Systems and Certification, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK, Certificate Number: US97/10267,

Medical Device Directive 93/42/EEC monitoring and supervision by SGS Belgium NV., SGS House Noorderlaan, 87 2030, Antwerp, Belgium., as Notified Body 1639 , Certificate Number: US19/819943504

Engineering Representative

Name: William Daniels Signature: William Daniels Date: 12/4/19

Site Quality Representative

Name: Ken Chapman Signature: Ken Chapman Date: 12/4/19

Regulatory Affairs Representative

Name: Elijah Wreh Signature: [illegible] Date: 09-Dec-19

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

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of oxygen cylinders with regulators.
Manufacture of hospital beds and oxygen concentrators.
Servicing of oxygen concentrators.

This certificate is valid from 12 April 2019 until 15 September 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 September 2021
Issue 17. Certified since 30 June 1997

Expiry date of last certificate: 15 September 2018
End date of last recertification audit: 25 October 2018

Authorised by

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

HC SGS 13485 2016 0118