



Yes, you can.<sup>2</sup>

### 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 Platinum AW Series Oxygen Concentrators

**Model(s)/Code(s):** IRC9LXO2AWQ

**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 Westfälica  
Country: Deutschland

is (are) in conformity with;

Medical Device Directive 93/42/EEC - Annex VII, 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),

IEC 60601-1 Issued: 2012/08/20 ED 3.1  
IEC 62366:2007 Ed.1  
EN ISO 13485:2012  
BS EN 15223-1:2012  
EN 62366:2015

IEC 60601-1-2 Issued: 2007/03/30 Ed: 3  
IEC 60601-1-11:2015 Ed.2  
EN ISO 14971:2012  
EN 1041:2008

IEC 60601-1-6:2010 Ed.3  
ISO 80601-2-69 Issued: 2014/07/15 Ed: 1  
EN ISO 15001:2011  
EN 55011:2009/A1:2010

and using a quality management system certified to ISO 13485: 2003 by SGS United Kingdom Ltd., Systems and Certification, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, U.K, Certificate Number: US97/10267,

Medical Device Directive 93/42/EEC monitoring and supervision by SGS United Kingdom Ltd., 202B Worle Parkway, Weston-super-Mare, BS22 6WK, U.K., as Notified Body 0120, Certificate Number: US11/82188

**Engineering Representative**

Name: William Daniels

Signature: 

Date: 11/14/17

**Site Quality Representative**

Name: Jeff Manno

Signature: 

Date: 11/14/17

**Regulatory Affairs Representative**

Name: Elijah Wreh

Signature: 

Date: 14-Nov-17