



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 Platinum 9 Oxygen Concentrator

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 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: *Elijah Wreh* Date: 09-Dec-19