CE DECLARATION OF CONFORMITY / DÉCLARATION CE DE CONFORMITÉ (MDD)		Invacare Yes, you can.
QUALITY SYSTEM FORM: FM-CP03-007b	**REVISION LEVEL:** G	

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

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

GMDN Code(s): 31321

Model(s)/Code(s): IRC5PO2VAW

Basic UDI-DI: 08414471Perfecto2VFQ

with the following locations;

Manufacturer Invacare Corporation
Address: One Invacare Way
City, State, Province: Elyria, OH 40435
Country: United States of America

EU Representative: Invacare GmbH
Address: Am Achener Hof 8
City, State, Province: 88316 Isny
Country: Germany

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: 6/5/2021

Site Quality Representative

Name: Donald Beatty Signature: Donald Beatty Date: 06/04/2021

Regulatory Affairs Representative

Name: Tyler Krueger Signature: Tyler Krueger Date: 6/4/2021