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

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

Product Name/Designation:

Invacare® Platinum® Mobile Oxygen Concentrator

GMDN Code(s): 31321

Model(s)/Code(s): POC1-100C-EU, POC1-110-EU, POC1-115-EU
POC1-130-EU, POC1-140, POC1-150

Basic UDI-DI: 08414471PlatinumMobileDA

with the following locations;

Manufacturer Invacare Corporation	EU Representative: Invacare GmbH
Address: One Invacare Way	Address: Am Achener Hof 8
City, State, Province: Elyria, OH 44035	City, State, Province: 88316 Isny
Country: United States of America	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 14971:2012	ISO 10993-11:2010	ISO 18562-2:2017	EN 60601-1-6:2010	EN 62366:2008
ISO 10993-1:2009	ISO 18562-1:2017	ISO 18562-3:2017	EN 60601-1-8:2014	ISO 80601-2-67:2014
ISO 10993-5:2009	ANSI C63.27	EN 60601-1:2006	EN 60601-1-11:2015	ISO 80601-2-69:2014
ISO 10993-10:2010	ISO 15223-1:2016	EN 60601-1-2:2015	EN 62304:2006	

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: Ronald Tucker Signature: Ron Tucker Date: 06/03/2021

Regulatory Affairs Representative

Name: Tyler Krueger Signature: Tyler Krueger Date: 06/03/2021