



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

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

Product Name/Designation: Invacare Platinum Mobile Oxygen Concentrator

Model(s)/Code(s): POC1-100B-EU, POC1-110-EU, POC1-115-EU, POC1-130-EU, POC1-140, POC1-150
GMDN Number: 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: Germany

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),

EN ISO 10993-1:2009	EN ISO 10993-5:2009	
EN ISO 14971:2012		
EN 60601-1:2012	EN 60601-1-2:2014	EN 60601-1-6:2010
EN 60601-1-8:2012	EN 60601-1-11:2015	
EN 62304:2006/AC:2008	EN 62366:2008	
EN ISO 80601-2-69:2014		

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.

Signed by: William Daniels Date: 4/25/2017 On behalf of: Invacare Corp.

Name: William Daniels Title: Engineering Manager

Signed by: Jeffrey Mauna Date: 4/25/2017 On behalf of: Invacare Corp.

Name: Jeffrey Mauna Title: Site Quality Manager

Signed by: Erjahn Wreh Date: 25-Apr-17 On behalf of: Invacare Corp.

Name: Erjahn Wreh Title: Regulatory Affairs Manager