



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 Perfecto2 Series Oxygen Concentrators

Model(s)/Code(s): IRC5PO2VAW

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 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 Worlc 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