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 Perfecto2 series Oxygen Concentrators

Model(s)/Code(s): IRC5PO2AW, IRC5PO2VAW

with the following locations;

Manufacturer: Invacare Rehabilitation Equipment (Suzhou) Co., Ltd.
Address: No. 5 Wei Xi Road
City, State, Province: SIP, Suzhou, Jiangsu
Country: P.R.C. 215121

EU Representative: Invacare Deutschland GmbH
Address: Kleistrasse 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 13485:2012
EN ISO 14971:2012
EN ISO 8359:2009, AMD 1:2012
EN 60601-1:1990:, A1:1993, A2:1995
EN 60601-1-2:2007

and using a quality management system certified to ISO 13485: 2003 by DET Norske Veritas, Certificate Number: 32085-2008-AQ-RGC-NA,

with Medical Device Directive 93/42/EEC monitoring and supervision by DNV Business Assurance, as Notified Body 0434 , Certificate Number: 83877-2010-CE-RGC-NA 2.0 to Article 11.3a and Annex II (excluding Section 4).

Signed by: [signature] Date: 8/1/14 On behalf of: INVACARE CORP.
Name: DAVID MAHLO FOR DOUG UELMEN Title: DIRECTOR CORPORATE RELIABILITY

Signed by: [signature] Date: 8/6/2014 On behalf of: Invacare Suzhou
Name: Jake Hong Title: Plant Quality manager

Signed by: [signature] Date: 8/12/2014 On behalf of: Invacare EU
Name: Andries Romauer Title: Dir of Quality and Regulatory Affairs