EC Declaration of Conformity

Manufacturer:	Invacare Rehabilitation Equipment (Suzhou) Co., Ltd.	EU Representative:	Invacare Deutschland GmbH
Address:	No. 5 Wei Xi Road	Address:	Kleiststrasse 49, D-32457
City, State, Province:	SIP, Suzhou, Jiangsu	City, State, Province:	Porta Westfalica
Country:	P.R.C. 215121	Country:	Deutschland

Declares that the medical device(s) described hereafter

Product Name: Perfecto2 AW Concentrators
Models: IRC5PO2AW
IRC5PO2VAW

Having a classification of IIausing Annex IX rule 11 is (are) in conformity with the essential requirements and provisions of Council Directive 93/42/EEC, per Annex VII, is (are) in conformance with the following standard(s):
EN ISO 13485:2012
EN ISO 14971:2012
EN ISO 15223-1:2012
EN 1041:2008
EN ISO 8359:2009
EN 60601-1:1990+ A1:1993+A2:1995
EN 60601-1-2:2007
IEC 61000-3-2:2009
IEC 61000-3-3:2008

And is (are) designed and manufactured under a quality management system, certified to ISO 13485:2003 byDET Norske Veritas, Certificate Number:32085-2008-AQ-RGC-NA and assessed for conformity to Council Directive 93/42/EEC as amended on medical devices described in Article 11.3.a and Annex V by DNV Business Assurance , Notified Body 0434 , Certificate 83877-2010-CE-RGC-NA

I, the undersigned, hereby declare that the device specified above conforms to Directive 93/42/EEC

8/13/2013

Signature Date
Name: Jim Qi
Title: Quality Manager, China
On behalf of: Invacare Rehabilitation Equipment (Suzhou) Co.,Ltd

Aug/15/2013

Signature Date
Name: Andres Romann
Title: Director.Quality and Regulatory Affairs
On behalf of: Europe