



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: Pronto Air Personal Transporter Chair - EU

Model(s)/Code(s):

with the following locations;

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

EU Representative: Invacare Deutschland, GmbH
Address: Kleiststrasse 49
City, State, Province: D-32457 Porta Westfalica
Country: Germany

is (are) in conformity with;

Medical Device Directive 93/42/EEC - Annex VI as classification I using Annex IX - Rule 1,

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 14971:2012
EN12184:2014
EN 1021, Sections 1, 2:2006

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

Signed by:

Date: 9/11/2014

On behalf of: INVACARE GSP

Name:

Douglas Heumen

Title:

SVP QA/RA

Signed by:

Date: 9/18/2014

On behalf of: Invacare Suzhou

Name:

Jake Hong

Title:

Plant Quality Manager

Signed by:

Date: 9/19/2014

On behalf of: IVC Porta Westfalica

Name:

Peter Heumen

Title:

Quality Manager