EC Declaration of Conformity

Manufacturer:	Invacare Corporation	EU Representative:	Invacare Deutschland GmbH
Address:	2101 E. Lake Mary Blvd.	Address:	Kleiststrasse 49, D-32457
City, State, Province:	Sanford, Florida 32773	City, State, Province:	Porta Westfalica
Country:	United States of America	Country:	Germany

Declares that the medical device(s) described hereafter

Product Name: HomeFill Cylinder Assembly with integrated regulator and/or conserving device

Models: Conserving Flow: HF2ECE6, HF2ECE9, HF2PCE6A, HF2PCE8, HF2PCE9A
Continuous Flow: HF2RE9, HF2RE9ES, HF2RE9AL

Having a classification of IIb using 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 10524-3:2006
EN ISO 14971:2012
EN ISO 18779:2005
PED 97/23/EC, Category III assemblies using Conformity Assessment Module H

And is (are) designed and manufactured under a quality management system, certified to ISO 13485:2003 by SGS United Kingdom Ltd, Systems and Services Certification, Certificate Number: US97/10267 and for Directive 93/42/EEC on medical devices, Annex II (excluding Section 4) by SGS United Kingdom Ltd., Notified Body 0120, Certificate US98/12047.

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

Signature: William Hoffman 8/30/13 Date	Signature: Jeff Manno 08/27/13 Date
Name: WILLIAM HOFFMAN	Name: JEFF MANNO
Title: DIRECTOR R/A	Title: QUALITY MANAGER
On behalf of: Invacare Corporation	On behalf of: Invacare Corporation