

CE DECLARATION OF CONFORMITY / DÉCLARATION CE DE CONFORMITÉ (MDD)

QUALITY SYSTEM FORM: FM-CP03-007b

REVISION LEVEL: G



Under sole responsibility, the undersigned hereby certify that the medical device(s) described hereinafter as;

Product Name/Designation:

HomeFill II AW Cylinder Assemblies

GMDN Code(s): 47225

Model(s)/Code(s):

Conserving Flow: HF2ECE6, HF2ECE9, HF2PCE6A, HF2PCE9A
 Continuous Flow: HF2RE9ES, HF2RE9AL

Basic UDI-DI: 08414471Homefill2CylB6

with the following locations;

Manufacturer Invacare Corporation
 Address: One Invacare Way
 City, State, Province: Elyria, OH 44035
 Country: United States of America

EU Representative: Invacare GmbH
 Address: Am Achener Hof 8
 City, State, Province: 88316 Isny
 Country: Germany

is (are) in conformity with;

Medical Device Directive 93/42/EEC - Annex V as classification IIb 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 1041:2008 | ISO 7866:2012 | ISO 10524-3:2005 | ISO 10993-1:2009 | ISO 10993-17:2012 |
| EN ISO 14971:2012 | ISO 15001:2010 | ISO 15223-1:2016 | ISO 80601-2-67:2014 | IEC 62366-1:2015 |
| IEC 60601-1:2005 | ISO 10524-1:2006 | | | |

and using a quality management system certified to ISO 13485: 2016 by SGS United Kingdom Ltd., Systems and Certification, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK, Certificate Number: US97/10267,

Medical Device Directive 93/42/EEC monitoring and supervision by SGS Belgium NV., SGS House Noorderlaan, 87 2030, Antwerp, Belgium, as Notified Body 1639, Certificate Number: US19/819943504.

Engineering Representative

Name: William Daniels

Signature:

Date: 7/21/22

Site Quality Representative

Name: Donald Beatty

Signature: See Attached

Date: 7/21/2022

Regulatory Affairs Representative

Name: Tyler Krueger

Signature:

Date: 7/21/2022

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Engineering Representative

Name: William Daniels Signature: _____ Date: _____

Site Quality Representative

Name: Donald Beatty Signature:  Date: 07/21/2022

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