

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: Invacare® HomeFill® II Compressor **GMDN Code(s):** 61605

Model(s)/Code(s): IOH200AW

Basic UDI-DI: 08414471HomeFill2WB

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 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 1041:2013 | ISO 10993-10:2010 | ISO 15001:2010 | IEC 60601-1-2:2014 | IEC 62304:2006 |
| ISO 10993-1:2009 | ISO 10993-11:2010 | ISO 15223-1:2016 | IEC 60601-1-6:2010 | IEC 62366-1:2015 |
| ISO 10993-5:2009 | EN ISO 14971:2012 | IEC 60601-1-11:2015 | IEC 60601-1: IEC 60601-1:2005+AMD1:2012 | |

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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Name: William Daniels Signature: _____ Date: _____

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