

**CE DECLARATION OF CONFORMITY / DÉCLARATION CE DE CONFORMITÉ (PED)**

QUALITY SYSTEM FORM: FM-CP03-007c

REVISION LEVEL: F



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

**Product Name/Designation:** HomeFill Cylinder Assembly with Integral Regulator or Conserver Device

Pressure vessel following conformity assessment procedures B + F.

Conserving Flow Regulator with integrated burst disk following conformity assessment procedure B + D.

Continuous Flow Regulator with integrated burst disk following conformity assessment procedures B + D.

**Model(s)/Code(s):**

Conserving Flow: HF2ECE6, HF2ECE9, HF2PCE6A, HF2PCE9A

Continuous Flow: HF2RE9ES, HF2RE9AL

**GMDN Code(s):** 47225 - Oxygen Refillable Cylinder

with the following locations

**Manufacturer:** Invacare Corporation  
**Address:** One Invacare Way  
**City, State, Province:** Elyria, Ohio 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 the requirements of Council Directive 2014/68/EU for using an Annex II classification of Category II for ML6 and III for M9 using Conformity Assessment Module H applying the following harmonized PED standard(s);

|                      |                     |                     |                    |
|----------------------|---------------------|---------------------|--------------------|
| EN ISO 10524-1:2006  | EN ISO 10524-3:2006 | EN ISO 14971:2012   | EN ISO 18779:2005  |
| EN ISO 13485:2012    | EN ISO 15001:2011   | EN ISO 15223-1:2012 | ISO 10993 – 1:2009 |
| EN ISO 10993-17:2012 | EN ISO 7866:1999    |                     |                    |

The following Technical Specification(s):

|                     |                  |                  |
|---------------------|------------------|------------------|
| ISO 80601-2-67:2014 | IEC 62366-1:2015 | IEC 60601-1:2005 |
|---------------------|------------------|------------------|

and designed and manufactured under a Quality Management System certified to Module H of the Pressure Equipment Directive (2014/68/EU)

by SGS Portugal, S.A., Industrial Services, Pólo Tecnológico de Lisboa, R. Cupertino de Miranda, Lt 6, Piso 0 e 1, 1600-546 Lisboa - Portugal, Notified Body No. 1155, Certificate Number: PTC20.09765.5120.

Pressure Equipment Directive 2014/68/EU monitoring and supervision by SGS Portugal, S.A., Industrial Services, Pólo Tecnológico de Lisboa, R. Cupertino de Miranda, Lt 6, Piso 0 e 1, 1600-546 Lisboa - Portugal, as Notified Body No. 1155, Certificate Number: PTC20.09765.5120

The fulfilment of essential safety requirements set out in Annex I of Council Directive 2014/68/EU has been demonstrated.

ICO-162428

Template Info: T-HQ05-001-001c Rev. Level: A ICO-159360 Issue Date: Mar. 16, 2018

FORM ISSUE DATE: JAN 25 2021

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**Engineering Representative**

Name: William Daniels Signature: See attached Date: 07/21/2022

**Site Quality Representative**

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

**Regulatory Affairs Representative**

Name: Tyler Krueger Signature:  Date: 7/21/2022

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Engineering Representative

Name: William Daniels

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7/21/22

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