

# EF-0938 – UKCA Declaration of Conformity

Version 1



**We declare under our sole responsibility that the product listed below**

**Product description, Code, Type, Model  
Intended purpose**

Invacare Softform Premier Active 2 Mattress  
Code (product line): PL3297, PL3298, PL3631  
*This pressure redistribution mattress and control unit are intended to be used in conjunction with an appropriately sized bed frame. The mattress can be used safely in static mode for static pressure redistribution, or in dynamic mode should an alternating pressure support surface be required.*

**Basic UDI-DI:**

505505-PREMIERACTIVE2

**Manufactured by:**

INVACARE UK  
Unit 4, Pencoed Technology Park  
Bridgend, CF35 5AQ  
United Kingdom

**Single registration number (SRN)**

GB-MF-000007111



Invacare Portugal Lda.  
Rua Estrada Velha, 949  
4465-784 Leca do Balio

**United Kingdom Responsible Person (UKRP)**

N/A

**meets all the provisions of the Part II UK MDR 2002 (as amended) which apply to it.**

**Device Classification according to Directive 93/42/EC, Annex IX**

**Class I**

**Applied harmonised standards, designated standards,  
national standards or other normative documents**

BS 7177: 2008+A1:2011 Medium Hazard (BS6807 Crib 5)  
EN 597-1 & 2:2015  
ISO 10993-5: 2009  
BS EN ISO14971: 2019  
EN 60601-1-2:2015/IEC60601-2:2014  
IEC 60601-1-2005 (3rd edition) + Corr. 1:2006  
2:2007+A1:2012  
IEC 60601-1-2:2014, EN 60601-1-2:2015, IEC60601-1-1:2015 Clause 12 EN 60601-1-11 Clause 12  
ISO 20342:1-2022 (7/10)

**Initial date of first UKCA Declaration of Conformity**

22-May-2024

**Place and issue date:** Pencoed, 22-May-2024

**Operations Manager**

Darren Swetman

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Yes, you can.

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