

EF-0938 – UKCA Declaration of Conformity

Version 2



Yes, you can.

Product name	Invacare Softform Premier Active 2 Mattress PL3297, PL3298, PL3631
Basic UDI-DI	505505-PREMIERACTIVE2
Intended purpose	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.
Manufactured by	Invacare UK Operations Ltd, Pencoed Technology Park, Pencoed Bridgend, CF35 5AQ
Manufacturer Single Registration Number (SRN)	GB-MF-000007111
Authorized Representative (EU-REP)	Invacare (Portugal), Unipessoal, Lda. Rua Estrada Velha, 949 4465-784 Leca do Balio Portugal
Authorized Representative SRN	PT-AR-000006129
United Kingdom Responsible Person (UKRP)	N/A

This UKCA declaration of conformity is issued under the sole responsibility of the manufacturer.

Device Classification according to Directive 93/42/EC, Annex IX	Class I
The object of the declaration is in conformity with the relevant legislation:	UK MDR 2002 (As amended) REACH 1907/2006, RoHS 2011/65/EU,
Applied harmonised standards, common specifications, 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 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 Declaration of Conformity	01 October 2012

Place and issue date:

Operations Manager

Pencoed, 01-OCT-2025

Darren Swetman,