

EF-0938 – UKCA Declaration of Conformity

Version 2



Yes, you can.

Product name	Softform Mattress Range (Softform Premier, Softform Premier Original, Softform Premier Visco, Softform Maxiglide, Softform Ampla)
Basic UDI-DI	505505-SOFTFORMMATTRESS6K
Intended purpose	These mattresses are intended to deliver effective pressure reduction and postural support to users. It is intended to be used in conjunction with an appropriately sized bed frame as part of an overall pressure injury prevention program of care.
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	EN 597-1 & 2: 2015 ISO 10993-5: 2009 ISO 9999:2022 BS EN ISO 14971: 2019/A11:2021 ISO 20342-7/10:2021
Initial date of first Declaration of Conformity	November 1998

Place and issue date:

Pencoed, 16-OCT-2026

Regulatory Affairs Manager

Renee de Beet

Electronically signed by: Renee de Beet
Reason: Reviewer/Approver - I have reviewed and approve this document.
Date: 16-Oct-2026 10:56:03 GMT+2