EF-0938 - UKCA Declaration of Conformity





We declare under our sole responsibility that the product listed below

Product description, Code, Type, Model Invacare Essential Mattress Range

Intended purpose Code (product line):

PL3296

This pressure redistribution mattress is intended to be used in conjunction with an appropriately sized bed frame, as part of an overall pressure ulcer prevention program of

care.

Basic UDI-DI: 505505-ESSENTIALMATTRESS

Manufactured by: INVACARE UK

Unit 4, Pencoed Technology Park

Bridgend, CF35 5AQ United Kingdom

Single registration number (SRN) GB-MF-000007111

EC REP 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

EN 597-1 & 2:2016
ISO 10993-5:2009

ISO 9999:2022

BS EN ISO 14971:2019/A11:2021

ISO 20342:1-2022 (7/10)

ISO 21856:2022

Initial date of first UKCA Declaration of Conformity 11-Oct-2023

Place and issue date: Pencoed 11-Oct-2023 Operations Manager

Darren Swetman

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