

Declaration of Conformity



The Supplier



Pressure Care Management Ltd
Unit 2 Edison Gate, West Portway, Andover SP10 3SE

The Authorized Representative



Vikta ApS (DK) Brydehusvej 23, 2750 Ballerup, DK

This company and its accredited representative declares that the products listed below are their sole responsibility, and satisfy the requirements of the standards set out in the following:

The Directives



Regulation (EU) 2017/745 (EU MDR) of the European Parliament and of the Council of 5 April 2017

The Product



Description

Fluidized Positioner

Name/type

Flo Form

Device classification

Class 1

Code	UDI numbers	Code	UDI numbers
FFU400	05745001142360	FF9015	05745001142315
FFT55	05745001142353	FF7010	05745001142308
FFT40	05745001142346	FF2028	05745001142292
FFT30	05745001142339	FF1824	05745001142285
FFS100	05745001142322	FF1220	05745001142278

Harmonized standards applicable to the assessment for this declaration include:



Risk Management ISO 14971:2019 Quality control: ISO 13485:2016
Labelling ISO 15223-1:2023(en) Information ISO 20417:2021

Declaration

Place of declaration	Stafford
Name of authorized person	P H Godden
Year of attestation	2025
Date of issue	21st February 2025
Certificate number	2080.2408.CE UK3