

Declaration of Conformity



The Manufacturer

i Vikta Ltd
Unit 2 Edison Gate, West Portway, Andover SP10 3SE

The Authorized Representative

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

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

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

The Product

i Description	Positioning Cushion
Name/type	PosiPerle
Device classification	Class 1
Code	Product number 30180--
UDI numbers (Typical)	05745001142186,-179,-063,-100,-087,-070,-148,-155,-193,-209,-216,-223,-230,-247,-094,-131,-124,-117,-162,-254,-261,-032,-025,-018,-049,-056..

Harmonized standards applicable to the assessment for this declaration include:

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

Declaration

i Place of declaration	Stafford
Year of attestation	2024
Date of issue	28 th August 2024
Name of authorized person	P H Godden
Certificate number	2080.2408.CE 3