

Declaration of Conformity



The Manufacturer



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

The Authorized Representative



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

This company and its accredited representative declare 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	Positioning Cushion
Name/type	PosiPerle
Device classification	Class 1

Code	UDI numbers	Code	UDI numbers	Code	UDI numbers
PP8040	05745001142230	PP8035	05745001142155	PP8033	05745001142070
PP8039	05745001142223	PP8034	05745001142148	PP8013	05745001142063
PP8038	05745001142216	PP8047	05745001142131	PP8050	05745001142056
PP8037	05745001142209	PP8048	05745001142124	PP8016	05745001142049
PP8036	05745001142193	PP8049	05745001142117	PP8018	05745001142018
PP8011	05745001142186	PP8014	05745001142100	PP8017	05745001142025
PP8012	05745001142179	PP8045	05745001142094	PP8046	05745001142032
PP8051	05745001142162	PP8015	05745001142087		

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	2080.2502 CE DK1