

Declaration of Conformity



The Manufacturer

i Vikta Ltd
Unit 2 Edison Gate, West Portway, Andover SP10 3SE Regd. no 11668502

The Authorized Representative

i 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

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

The Product

i Description	Continuous Lateral Tilting System
Name/type	KOMFITILT
Device classification	Class 1
Code	VK3205
UDI numbers (Typical)	



05745001142001

Harmonized standards applicable to the assessment for this declaration include:

i IEC 60601-1:2005+A1:2012 and EN 60601-1:2006+A11:2011+A1:2013+A12:2014
EN 60601-1-2:2015 (EN 55011:2009+A1:2010) EN 60601-1-2:2015
DIN EN 10993-5 (L929), DIN EN ISO 10993-10:2014
ISO 14971:2012 Medical devices IEC 62304:2006 Medical device software
EC 62366:2007 Usability engineering

Declaration

i Place of declaration	Stafford
Year of attestation	2023
Date of issue	22 nd September 2023
Name of authorized person	P H Godden
Certificate number	G2064.2