



# Declaration Of Conformity



## MDR(EU) 2017/745 Statics Mattress & Cushions

Product Identification		
1.	Unique identification code of the product type:	Avon, Yorkshire, Somerset, Devon, Dorset, Kent, Durham, Cumbria, Berkshire, Essex, Norfolk, Sussex, Bambino, Suffolk
2.	Type batch or serial number or any other element allowing identification of the product:	AV-111, YORK-118, SOM-112, DEV-113, DOR-114, KEN-115, DUR-115, CUM-116, BERK-117, ESS-131, NOR-141, SUS-999, BAMB-117, SUF-201
3.	Intended use or uses in accordance with the applicable harmonised standard, as foreseen by the manufacturer:	Pressure Relief Mattresses & Cushions for use within the Healthcare Industry. These are support surfaces aimed at distributing body weight over a large area to prevent/reduce pressure ulcers.
4.	Basic UDI-DI	50564619Statics3P
Manufacturer		
5.	Name:	Herida Healthcare Ltd.
6.	Address:	Herida House Unit2, Leeds 27 Industrial Estate Bruntcliffe Avenue, Morley Leeds, LS27 0LL, UK  +44 (0)800 193 6030 www.heridahealthcare.co.uk
7.	SRN:	GB-MF-000028325
Authorised Representative in Europe		
8.	Name:	Emergo Europe
9.	Address:	Prinsessegracht 20 2514 AP The Hague The Netherlands
10.	SRN:	NL-AR-000000116
Means of Conformity		
Herida Healthcare Ltd. declares that the products listed have been classified as Class 1. Fulfil the requirement of the Regulations of MDR (EU) 2017/745 which apply to the device.		
11.	Route to Conformance:	Annexe IX / Rule 1
12.	Risk Classification:	Class I
13.	In case of a declaration of conformity concerning a medical device covered by a harmonised standard:	BS EN ISO 13485:2016; BS EN ISO 14971:2012; BS EN ISO 15223-1:2020; BS EN ISO 10993-1:2018; BS7177:2008; BS7176:2008; BS EN ISO 15223-1:2016
14.	Date:	01/09/2022
15.	Name / Position:	John Kay Director
16.	Place of Issue:	Herida House Unit2, Leeds 27 Industrial Estate Bruntcliffe Avenue, Morley Leeds, LS27 0LL, UK
17.	Signature / Statement:	<i>John Kay</i> This Declaration Of Conformity is issued under the sole responsibility of the manufacturer.