Declaration of Conformity TF-ZBd-14
Basic UDI-DI: 57000021919-ZBD-M5

Declaration of Conformity for Balanze Duvet

The device is in conformity with Medical Device regulation 2017 /745.

Name and address of Manufacturer	ZiboCare Denmark ApS Præstemarksvej 67 8700 Horsens Denmark		
SRN Number of the Manufacturer	DK-MF-000029223		
Basic UDI-DI	57000021919-ZBD-M5		
Reference number		140 x 200 cm	140x 220 cm
	4 kg classic -	700032003	
	6 kg classic	700032004	700032201
	8 kg classic	700032005	700032202
	10 kg classic	700032006	700032203
	12 kg classic	700032007	700032204
	14 kg classic	700032008	700032205
	4 kg sensitiv	700032101	
	6 kg Sensitiv	700032102	700032301
	8 kg Sensitiv	700032103	700032302
	10 kg Sensitiv	700032104	700032303
	12 kg Sensitiv	700032105	700032304
	14 kg Sensitiv	700032106	700032305
		100x 140 cm	
	3 kg junior classic	700032001	
	5 kg junior classic	700032002	
	3 kg junior sensitive	700032107	
	5 kg junior sensitiv	700032108	
Product name/Trade name	Balanze Duvet		
Intended purpose	The duvet is intended to ease sleep problems. The duvet enhances body awareness and stimulates the feedback mechanisms in the body through a		

	combination of sensoric and tactile stimulation. The sensoric stimulation is caused by the weight of the plaid and the tactile stimulation is the feedback from the chains during use. The combined stimulation supports the user in relaxing, feeling grounded and safe.
Intended Users	Persons (Children from the age of 3 years) with sleep problems suffering from fx: Stress, ADHD, Autism, dementia, anxiety, inner turmoil, overwhelming thoughts, or PTSD.
Risk class	Medical Device Regulation (EU) 2017/745. With reference to article 51 of the MDR and in accordance with Annex VIII the classification of the product is: **Class I, short term use**
Standards	EC 1907/2006 – REACH OEKO-TEX STANDARD 100 ISO 21856:2022 Assitive Products – General requirements and tests ISO 21801-1:2020 Cognitive accessibility
Notified body name and number (if relevant)	Class I Medical Device. Selfdeclaration, therefore, no Notified Body

This EU Declaration of Conformity is issued under the sole responsibility of:

ZiboCare Denmark ApS
Præstemarksvej 67
8700 Horsens
Denmark

21.11.2023 Horsens

Jesper Skov Rosenbrock
Managing Director of ZiboCare Denmark

Revision + Date	Change	Responsible
Version 1.0 2023.06.07	Edited	DKS
Version 1.1 2023.21.11	Date and signer added	DKS