Declaration of Conformity TF-ZMBS-14
Basic UDI-DI: 57000021919-ZMBS-KV

Declaration of Conformity for BASIS - and BASIS TOP

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-ZMBS-KV
Reference number	BASIS: REF 8020014BASIS: 80cm x 200cm x 14cm REF 8320014BASIS: 83cm x 200cm x 14cm REF 8820014BASIS: 88cm x 200cm x 14cm BASIS TOP: REF 802007BASIS: 80cm x 200cm x 7cm REF 852007BASIS: 85cm x 200cm x 7cm REF 902007BASIS: 90cm x 200cm x 7cm REF 1202007BASIS: 120cm x 200cm x 7cm
Product name/Trade name	BASIS - and BASIS TOP
Intended purpose	Preventive pressure ulcer treatment in the care sector additional to professional care and treatment.
Intended Users	Patients who have a low to moderate risk of developing pressure ulcers according to the Braden Scale. The intended user weight for BASIS – and BASIS TOP mattress is up to 150kg.
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, Rule I, Short term use**
Standards	Oeko-Tex Standard 100: OEKO-TEX® Standard 100 is a product-certification, setting requirements to the contents of the chemical components, that are – or are likely to cause damage to the human body tissues. EN ISO 20342-1: 2022 Assisted products for tissue integrity when lying down. EN ISO 21856:2022 Assistive products – General requirements and test methods.
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

28.06.2023 Horsens

Managing Director of ZiboCare Denmark: J.Denker Jeannette Denker