Declaration of conformity for ZiboCare Mono

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

	Information
Name and address of Manufacturer	ZiboCare Denmark A/S Præstemarksvej 67 8700 Horsens
Basic UDI-DI	570000101233Y8
Product name/Trade name	Mono mattress, wound grad 0-3, 0-150 kg
Risk class	Class I Medical Device – Rule I Annex VIII of MDR 745/2017
Reference to standards if applicable	No product standards applicable
Notified body name and number (if relevant)	Class I Medical Device. Self-declaration, therefor no Notified Body

The Intended use:
Standard foam mattress for general use for pressure ulcer treatment and prevention in the care sector.
Userweight: 0 – 150 Kg. Pressure wound grade 0 to 3 (EUPAP).

It is recommended to reposition the patient on a regular basis, time for this to be estimated by the care staff according to the state of the patient.

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

ZiboCare Denmark A/S
Præstemarksvej 67
8700 Horsens

Horsens, 2022.02.02

Jeannette B. Dencker, CEO
Name and signature

Revision	Date	Responsible	Change
1	2022-02-02	ERK	Intended use added and date updated