

EU Declaration of Conformity

Issuer's name and address

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SRN: NL-MF-000002013
Basic UDI-DI: 8719325611CB001XD
GMDN Code: 62826
Conformity: The canopy beds have been classified according to Annex VII and is in conformity with the general Safety and Performance requirements and provisions of the (EU) Medical Device Regulation 2017/745 and are in conformity with the relevant Harmonized standards:
Assessment route: ISO 13485:2021, ISO 14971:2019, ISO 15223-1:2021, ISO 20417:2021, ISO 10993

This EU Declaration of Conformity is issued under the sole responsibility of Human Protection B.V.

Ref Number	UDI-DI	Description	Classification
BT002	8719325611335	FeelSafe Basic	I, rule 13
X-BT002	8719325611373	FeelSafe Basic	
BT003	8719325611342	FeelSafe Transfer	
BT004	8719325611359	FeelSafe Pro	
X-BT004	8719325611786	FeelSafe Pro	
EA003	8719325475449	FeelSafe Go	
X-EA003	8719325475432	FeelSafe Go	
BT001A	8719325611779	FeelSafe Atlas	I, rule 1

Intended Use/Purpose

The canopy bed system provides a confined space with fewer external stimuli, which is achieved by containing the person in a secured environment.

Object of the declaration

This declaration of conformity is issued under the sole responsibility of Human Protection B.V. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices (article 19 and Annex IV).

Signature

Place and date: Tilburg, 20-06-2024

Kasper Brands, Managing Director

