

Human Protection B.V. Droogdokkeneiland 4 NL-5026 SR Tilburg Netherlands +31 (0)13 536 38 07

info@humanprotection.nl www.humanprotection.nl

EU Declaration of Conformity

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

Name

Human Protection B.V.

Address

Droogdokkeneiland 4

5026 SR Tilburg
The Netherlands

Phone

+31 (0) 13 536 38 07

Email

info@humanprotection.nl

SRN

NL-MF-000002013

Basic UDI-DI

87193256CCJ01M4

EMDN Code

V9099

GMDN Code

67400

UK REP

UKCA Experts Ltd, Dept 302, 43 Owsten Road

Dept 302, 43 Owston Road Carcroft, Doncaster, DN6 8DA

United Kingdom

CH REP

AR Experts, Certification Experts S.A.R.L.

Avenue de Gratta-Paille 2

1018 Lausanne Switzerland

Conformity

Assessment route

The CloudCuddle products have been classified according to Annex VIII and are 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:

ISO 13485:2016, ISO 14971:2019, ISO 15223-1-2021, ISO 20417:2021

Intended Use

Soothing and shielding bed security

Object of 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 in Annex I meet the provision of the Regulation (EU) MDR 2017/745 for medical devices (article 19 and Annex IV).

Kasper Brands, Managing Director

Place and date: Tilburg, 20-08-2025



Human Protection B.V. Droogdokkeneiland 4 NL-5026 SR Tilburg Netherlands +31 (0)13 536 38 07

info@humanprotection.nl www.humanprotection.nl

Annex I – List of Products

Ref Number	UDI-DI	Description	Classification
CCJ01.01	8719325611625	CloudCuddle Junior Cover	Class I, rule 1
CCJ01.02	8719325611618	CloudCuddle Junior Frame	Class I, rule 1
CCJ01.03	8719325611595	CloudCuddle Junior Sheet	Class I, rule 1
CCJ01.04	8719325611564	CloudCuddle Junior Pump	Class I, rule 1
CCJ01.05	8719325611557	CloudCuddle Junior Bag	Class I, rule 1
CCM01.01	8719325611472	CloudCuddle Maxx cover	Class I, rule 1
CCM01.02	8720618509000	CloudCuddle Maxx frame	Class I, rule 1
CCM01.03	8719325611489	CloudCuddle Maxx sheet	Class I, rule 1
CCM01.04	8719325611779	CloudCuddle Maxx pump	Class I, rule 1
CCM01.05	8719325611786	CloudCuddle Maxx bag	Class I, rule 1