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<br>5026 SR Tilburg<br>The Netherlands |
| **Phone** | +31 (0) 13 536 38 07 |
| **Email** | info@humanprotection.nl |
| **SRN** | NL-MF-000002013 |
| **Basic UDI-DI** | 87193256CCJ01M4 |
| **EMDN Code** | Y1899 |
| **GMDN Code** | 65683 |
| **UK REP** | UKCA Experts Ltd<br>6 Stanford Street<br>Nottingham<br>NG1 7BQ<br>UK |
| **CH REP** | AR Experts, Certification Experts S.A.R.L.<br>Avenue de Gratta-Paille 2<br>1018 Lausanne<br>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:<br>ISO 13485:2016, ISO 14971:2019, ISO 15223-1-2021, ISO 20417:2026 |
| **Intended Use** | See Annex I – List of products |
| **Object of Declaration** | This declaration of conformity is issued under the sole responsibility of Human Protection B.V.<br>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, 04-09-2026

human protection

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** | CCJ01 – CloudCuddle Junior |
| **Intended use** | The CloudCuddle Junior is intended to be used for soothing and shielding bed security |

Complete configuration of the CloudCuddle Junior system, consisting of the individual components.

| 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 |

In addition, the optional accessories listed below are available.

| REF Number | UDI-DI | Description | Classification |
|---|---|---|---|
| CCJ01.07 | 8720618509154 | CloudCuddle Junior incontinence sheet | Class I, rule 1 |

human protection

Human Protection B.V.
Droogdokkeneiland 4
NL-5026 SR Tilburg
Netherlands

+31 (0)13 536 38 07

info@humanprotection.nl
www.humanprotection.nl

| | |
|---|---|
| **REF** | CCM01 – CloudCuddle Maxx |
| **Intended use** | The CloudCuddle Maxx is intended to be used for soothing and shielding bed security |

Complete configuration of the CloudCuddle Maxx system, consisting of the individual components:

| REF Number | UDI-DI | Description | Classification |
|---|---|---|---|
| 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 |
| CCM01.06 | 8720892793027 | CloudCuddle Maxx quick release system | Class I, rule 1 |
| CCM01.08 | 8720892793034 | CloudCuddle Maxx stability set | Class I, rule 1 |

In addition, the optional accessories listed below are available.

| REF Number | UDI-DI | Description | Classification |
|---|---|---|---|
| CCM01.07 | 8720618509147 | CloudCuddle Maxx incontinence sheet | Class I, rule 1 |

human protection

Human Protection B.V.
Droogdokkeneiland 4
NL-5026 SR Tilburg
Netherlands

+31 (0)13 536 38 07

info@humanprotection.nl
www.humanprotection.nl

| | |
|---|---|
| **REF** | CCM05 – CloudCuddle Maxx 210cm |
| **Intended use** | The CloudCuddle Maxx 210cm is intended to be used for soothing and shielding bed security |

Complete configuration of the CloudCuddle Maxx 210cm system, consisting of the individual components:

| REF Number | UDI-DI | Description | Classification |
|---|---|---|---|
| CCM05.01 | 8720618509185 | CloudCuddle Maxx 210cm cover | Class I, rule 1 |
| CCM05.02 | 8720618509178 | CloudCuddle Maxx 210cm frame | Class I, rule 1 |
| CCM05.03 | 8720618509192 | CloudCuddle Maxx 210cm sheet | Class I, rule 1 |
| CCM01.04 | 8719325611779 | CloudCuddle Maxx pump | Class I, rule 1 |
| CCM05.05 | 8720618509208 | CloudCuddle Maxx 210cm bag | Class I, rule 1 |
| CCM01.06 | 8720892793027 | CloudCuddle Maxx quick release system | Class I, rule 1 |
| CCM01.08 | 8720892793034 | CloudCuddle Maxx stability set | Class I, rule 1 |