# DECLARATION OF CONFORMITY

## 1 Manufacturer

**Deron B.V.**
Willem Alexanderstraat 5
NL- 6691 EE Gendt
*SRN: NL-MF-000006051*

*Deron B.V. is in compliance with the standard UNI CEI EN ISO 13485:2021 certified by Kiwa Cermet Italia under registration number 11452-A-M, for the following products/services: Design and development, manufacturing, sales, storage, preservation, servicing, handling and delivery of medical mattresses and accessories.*

## 2 Product(s):

| |
|---|
| See appendix |

## 3 The product(s) described above is in conformity with:

| Title | Document No. |
|---|---|
| Medical Device Regulation | (EU) 2017/745 |

## 4 Additional information:

Conformity assessment procedure conform (EU) 2017/745 Medical Device Regulation (MDR), Annex II and Annex III.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Gendt, 2024-09-26

W.A. Grimberg
*CEO*

S. Vermaas
*PRRC*

## Appendix

Date: 2021-05-21

List of devices.

| Product and trade name | Product code/ catalogue number/ unambiguous ref. | Intended purpose | Risk class/ rule[1] | Basic UDI-DI[2] | EMDN |
|---|---|---|---|---|---|
| Hoes inco blauw 3zr | 20000 | Protect the medical mattress and maintain a hygienic patient surface \| Accessory to an active medical device (AD mattress) | Class I/Rule1 | 871897120000K7 | J01030101 – Mattress covers for medical beds |
| Hoes inco groen 3zr | 20100 | Protect the medical mattress and maintain a hygienic patient surface \| Accessory to an active medical device (AD mattress | Class I/Rule1 | 871897120100KC | J01030101 – Mattress covers for medical beds |
| Hoes inco indigo 3zr | 20200 | Protect the medical mattress and maintain a hygienic patient surface \| Accessory to an active medical | Class I/Rule1 | 871897120200KH | J01030101 – Mattress covers for medical beds |

[1] *See risk classification in Medical Device Regulation, annex VIII*

[2] *Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI*

| Product and trade name | Product code/ catalogue number/ unambiguous ref. | Intended purpose | Risk class/ rule[1] | Basic UDI-DI[2] | EMDN |
|---|---|---|---|---|---|
| | | device (AD mattress | | | |
| Hoes inco blauw/groen 3zr + opdr. 'This side up' | 20300 | Protect the medical mattress and maintain a hygienic patient surface \| Accessory to an active medical device (AD mattress | Class I/Rule1 | 871897120300KN | J01030101 – Mattress covers for medical beds |
| Hoes inco antraciet 3zr | 20500 | Protect the medical mattress and maintain a hygienic patient surface \| Accessory to an active medical device (AD mattress | Class I/Rule1 | 871897120500KY | J01030101 – Mattress covers for medical beds |