

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:

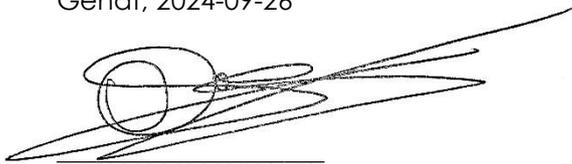
<u>Title</u>	<u>Document No.</u>
Medical Device Regulation	(EU) 2017/745

4 Additional information:

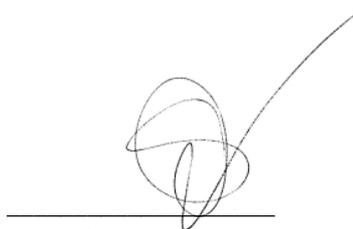
Conformity assessment procedure conform (EU) 2017/745 Medical Device Regulation (MDR), Annex II and Annex III.

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