

DECLARATION OF CONFORMITY

1 Manufacturer

Deron B.V.
 Willem Alexanderstraat 5
 6691 EE Gendt
 The Netherlands
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:

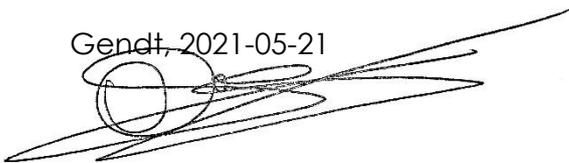
<u>Title</u>	<u>Document No.</u>
Medical Device Regulation	(EU) 2017/745

4 Additional information:

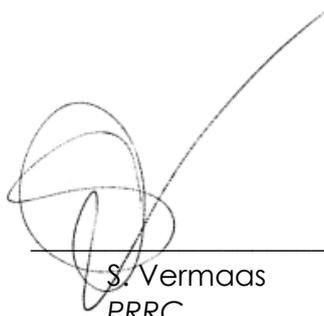
Conformity assessment procedure: Medical Device Regulation, Annex II & III

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

Gendt, 2021-05-21



 W.A. Grimberg
 CEO



 S. Vermaas
 PRRC

Appendix

List of devices.

Product and trade name	Product code/catalogue number/unambiguous ref.	Intended purpose	Risk class/rule ¹	Basic UDI-DI ²	EMDN
Zitkussen koudschuim hoes inco zwart / antislip 5cm	30050	AD Seat Cushion	Class I/ Rule 1	81791300509F	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen koudschuim hoes inco zwart / antislip 7cm	30070	AD Seat Cushion	Class I/ Rule 1	81791300709M	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim Medium hoes inco zwart / antislip 1zr 5cm	30250	AD Seat Cushion	Class I/ Rule 1	81791302509R	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim Medium hoes inco zwart / antislip 1zr 7cm	30270	AD Seat Cushion	Class I/ Rule 1	81791302709X	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim Soft hoes inco zwart / antislip 1zr 5cm	30350	AD Seat Cushion	Class I/ Rule 1	81791303509W	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim Soft hoes inco zwart / antislip 1zr 7cm	30370	AD Seat Cushion	Class I/ Rule 1	8179130370A4	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim Firm hoes inco zwart / antislip 1zr 5cm	30450	AD Seat Cushion	Class I/ Rule 1	8179130450A3	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim Firm hoes inco zwart / antislip 1zr 7cm	30470	AD Seat Cushion	Class I/ Rule 1	8179130470A9	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS

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
Zitkussen traagschuim extra Firm hoes inco zwart / antislip 5cm	30550	AD Seat Cushion	Class I/ Rule 1	8179130550A8	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim extra Firm hoes inco zwart / antislip 7cm	30570	AD Seat Cushion	Class I/ Rule 1	8179130570AE	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS
Zitkussen traagschuim combi hoes inco zwart / antislip 5cm	30950	AD Seat Cushion	Class I/ Rule 1	8179130950AU	V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS