

DECLARATION OF CONFORMITY

1 Manufacturer

Lima B.V.
 Nijverheidsweg 9
 NL- 6691 EZ Gendt
 SRN: **NL-MF-000009568**

Distributor

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

Lima B.V. is in compliance with the standard UNI CEI EN ISO 13485:2021 certified by Kiwa Cermet Italia under registration number 17797 - M, for the following products/services: Design & development, manufacturing, sales, storage, preservation, servicing, commissioning, handling and delivery of medical beds and accessories..

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 Medical Device Regulation (MDR)

4 Additional information:

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

In conformity with:

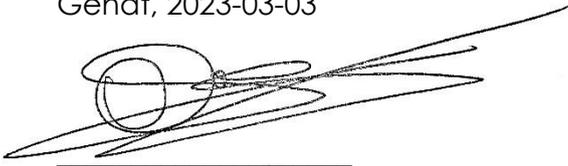
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint); IEC 60601-2-52:2009+AMD1:2015; IEC 60601-1-11:2015

Tested by: TÜV Rheinland®, Test Report No.: 26633401-02/2018

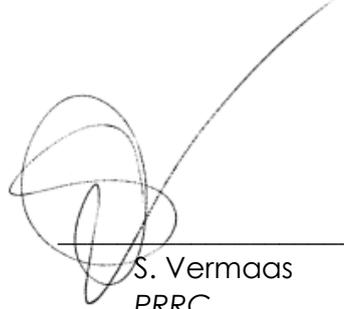
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This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Gendt, 2023-03-03



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
Lima 1000 Timeless	50100	Medical Bed	Class 1/ Rule 13	871897150100LD	V08060101 HOSPITAL/HOME CARE ELECTRIC MEDICAL BEDS
Lima 2000 Timeless Deluxe FullCare Exclusive FullCare Exclusive XL	50200	Medical Bed	Class 1/ Rule 13	871897150200LJ	V08060101 HOSPITAL/HOME CARE ELECTRIC 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