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:

Title	Document No.
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

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