# EC- DECLARATION OF CONFORMITY

Following the EC Regulation concerning medical devices MDR EU 2017/745, annex IV.

I, the undersigned, agent of the following manufacturer:

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**Belgium** **Single Registration NR: BE-MF-000000056**

Declare hereby under sole responsibility that the following product:

## Velino

## No.: 08557

**Basic UDI-DI: 5430002080CarebedsH4**

Medical device class I (non-invasive device), according MDR annex VIII, intended and made to treat, guard, alleviate or compensate diseases, injuries or handicaps of an adult,

when installed, maintained and used in accordance with the manual, the rules of good craftsmanship, and the intended purpose complies with all necessary safety requirements and other relevant provisions of annex I of:

## Medical Devices Regulation EU 2017/745

The following harmonised norms have been applied to indicate the conformity:

| | |
|---|---|
| **EN 60601-1** | Medical electrical equipment. Part 1: General requirements for basic safety and essential performance. |
| **EN 60601-1-2** | Medical electrical equipment. Part 1-2: General requirements for safety and essential performance – Secondary norm: Electromagnetic compatibility – Requirements and tests. |
| **EN 60601-2-52** | Medical electrical equipment. Part 2-52: Particular requirements for basic safety and essential performance of medical beds. |
| **EN ISO 14971** | Application of risk management to medical devices. |

The above-mentioned product has been designed, produced and checked in accordance with the quality management systems of **ISO 9001:2015** and **ISO 13485:2016**.

**Ingelmunster, 26/05/2020**

**Signature:**

**Haelvoet Vincent**
**Managing director**