# Declaration of Conformity

## APPROVALS

| | Prepared | Reviewed | Approved |
|---|---|---|---|
| **By** | Thomas Weidmann, COO  | Michael Woeedd, CCO  | Jason de Weerd, CEO  |
| **Date** | 2026/08/17 | 2026/08/20 | 2026/08/26 |

## VERSION HISTORY

| No. | Date | Version | Prepared | Reviewed | Approved | Feature changes compared with previous version |
|---|---|---|---|---|---|---|
| 1 | 2026/08/26 | 1 | Thomas Weidmann | Michael Woeedd | Jason de Weerd | initial |
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# EU Declaration of Conformity

## Regulation (EU) 2017/745 on Medical Devices (MDR)

1. Manufacturer: VITAL FJORD B.V.

   Address: Prinsengracht 353 A, 1016 HK Amsterdam, The Netherlands

   SRN: NL-MF-000056431

2. Statement of Responsibility:

This Declaration of Conformity is issued under the sole responsibility of VITAL FJORD. B.V.

3. Device Identification:

Product Name: Electric lift commode chair

Model/Type: C02-01-A001

Basic UDI-DI: 955103368C0201A001QQ

Intended Purpose: The device is intended to be used to transport patients who are unable to assist in their own transfer.

4. Risk Classification:

Class I, non-sterile, non-measuring, non-reusable surgical instrument.

Classification Rule: Rule 13 in accordance with Annex VIII of Regulation (EU) 2017/745 (MDR).

5. Conformity Assessment Procedure:

Conformity assessment procedure followed in accordance with Annex II and Annex III of Regulation (EU) 2017/745 (MDR).

6. Statement of Compliance:

The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR).

7. Common Specifications (CS) / Standards Applied:

References to the relevant harmonized standards or CS used in relation to which conformity is declared:

- EN ISO 13485:2016 (Quality management systems - Requirements for regulatory purposes)

- EN ISO 14971:2019 (Application of risk management to medical devices)

- EN 60601-1:2006/A1:2013 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)

- EN 60601-1-2:2015 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)

- EN 60601-1-6:2010/A1:2015 (Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability)

- EN 60601-1-11:2015 (Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical

electrical equipment and medical electrical systems used in the home healthcare environment)

- EN ISO 10993-1:2020 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process)

8. Signed for and on behalf of:

Place of Issue: Amsterdam, The Netherlands

Date of Issue: 2026-08-26

Signature: 

Name: Thomas Weidmann

Function/Title: COO