

Appendix 6 Declaration of conformity



EU DECLARATION OF CONFORMITY

We,

Focal Meditech
Droogdokkeneiland 19
5026 SP Tilburg
The Netherlands

registered in EUDAMED under the Single Registration Number NL-MF-000000536, hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

**Flowing⁺ (type number 607404),
and its accessories**

having the intended purpose: Flowing⁺ is a dynamic arm support system. It is designed for users requiring considerable compensation against gravity during movements of the human arm.

And have been registered under basic UDI-DI 87193276494FOCFW+PG, and classified as Class I, according to Annex VIII, Rule number 13,

and are in conformity with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are in conformity with the standards:

- | | |
|------------------|--|
| • EN 1041 | Information supplied by manufacturer of medical devices |
| • EN-ISO 9999 | Assistive products – Classification and terminology |
| • EN-ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| • EN-ISO 13485 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| • EN-ISO 14971 | Medical devices – Application of risk management to medical devices |
| • ISO 15223-1 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements |
| • EN-IEC 60529 | Degrees of protection provided by enclosures (IP code) |
| • EN-IEC 60601-1 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| • EN-IEC 62304 | Medical device software – Software life-cycle processes |

and are in conformity with the requirements of directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Signature:

A handwritten signature in blue ink, appearing to read "Paul Groenland", written over a horizontal line.

Tilburg, The Netherlands

Date: 20 November 2023
Name: Paul Groenland
Function: Managing Director

