

## EC DECLARATION OF CONFORMITY

We,

Focal Meditech  
Droogdokkeneiland 19  
5026 SP Tilburg  
The Netherlands

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

### Dowing<sup>2</sup> (type number 600817) and its accessories

having the intended purpose: Dowing<sup>2</sup> is a dynamic arm support. It is designed for persons having a need for considerable compensation against gravity during movements of the human arm.

and have been classified as Class I, according to Annex VIII, Rule number 1,

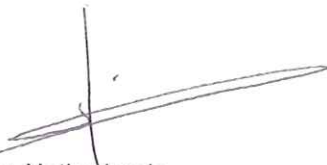
and are in conformity with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are in conformity with the standards:

- EN 1041 Information supplied by manufacturer of medical devices
- EN 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN 13485 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN 14971 Medical devices – Application of risk management to medical devices
- EN 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

and are in conformity with the requirements of directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 92/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

Signature:



Tilburg, The Netherlands

Date: 1 May 2020  
Name: Paul Groenland  
Function: Managing Director

 **Focal Meditech BV**  
Droogdokkeneiland 19  
5026 SP Tilburg

## Annexe 6 Déclaration de conformité



### EC DECLARATION OF CONFORMITY

We,

Focal Meditech  
Droogdokkeneiland 19  
5026 SP Tilburg  
The Netherlands

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

Gowing<sup>2</sup> (type number 605540)  
and its accessories

having the intended purpose: Gowing<sup>2</sup> is a dynamic arm support. It is designed for persons having a need for considerable compensation against gravity during movements of the human arm.

and have been 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 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN 13485 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN 14971 Medical devices – Application of risk management to medical devices
- EN 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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 be "Paul Groenland", written over a horizontal line.

Tilburg, The Netherlands

Date: 1 February 2020  
Name: Paul Groenland  
Function: Managing Director

 Focal Meditech BV  
Droogdokkeneiland 19  
5026 SP Tilburg