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,

Dowing² (type number 600817)
and its accessories

having the intended purpose: Dowing² 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

FOCAL meditech

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,

Gowing² (type number 605540)
and its accessories

having the intended purpose: Gowing² 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:

Tilburg, The Netherlands

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

Focal Meditech BV
Droogdokkeneiland 19
5026 SP Tilburg