



Declaration of Conformity

Finapres Medical Systems B.V.
Institutenweg 25
7521 PH Enschede
The Netherlands

Enschede, January 04, 2017

Declaration of conformity medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference number: 2020319CE01, first issued on 15 June 2002, by DEKRA Certification B.V., Arnhem, The Netherlands, with Notified Body Identification Number 0344.

The products conform to the required technical documentation in accordance with Annex VII of the Dutch law "Besluit Medische Hulpmiddelen" transposing the European Community Directives as the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

We declare that the CE marked products mentioned in the certificates meet the applicable provisions of the European Community Directive for Class IIa devices.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned in accordance with Annex V/VII of the European Community Directive. Conformity of production quality assurance stated in Annex V is confirmed by the CE Marking of Conformity certificate as issued by DEKRA Certification B.V.

This declaration covers a product list in the appendix.



Mr. Michiel Jannink
Managing Director

Annex: Product List

Product List

Finapres Medical Systems B.V.
Institutenweg 25
7521 PH Enschede
The Netherlands

Product List Finapres Medical Systems B.V.

This product list belongs to the Declaration of Conformity identified above and specifies the CE marked products concerned that Finapres Medical Systems B.V. distributes in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The following list identifies the products by name, model, version number and/or by serial number.

Product name	Class	Product model	Time related information
BeatScope	Ila	Version 1.1.a	Licence number: from 20142862
Finometer	Ila	Model-1	Serial number: from FM.1.1310.00976
Finometer	Ila	Model-2	Serial number: from FM.2.131105356
Portapres	Ila	Model-2	Serial number: from 13.08.PP.M2.00862
Finapres® NOVA with FEU	Ila		Serial number: from FNO140100019
Finapres® NOVA with FEU NC	Ila		Serial number: from FNO161000152