144877-19-04-08

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical devices, Annex II (4)

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the requirements of the directive.

Name of the manufacturer:

PulseCath B.V.

Headquarters: **Nieuwe Stationsstraat 20, 14th floor, 6811 KS Arnhem, The Netherlands**

Scope:

Catheter based ventricular circulatory support device and accessories
LV17

The certificate covers the following devices:

Name of the device	Intended use	Type	Model	Risk class
Catheter based left ventricular circulatory support device and accessories	circulatory support	LV17	PulseCath iVAC2L	III

This certificate is valid only with the system certificate No. **144876-19-04-08**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 65-G1-181101

Issue: 1
Issued: 08 April 2019
First issued: 08 April 2019
Start date of certified status: 08 April 2019

Expires:
07 April 2024

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