144876-19-04-08

EC CERTIFICATE

Full Quality Assurance System

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

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related 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

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*

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices.

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 65-CE-181101

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First issued: 08 April 2019
Start date of certified status: 08 April 2019

Expires:
07 April 2024

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