EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 on Medical devices
Annex IX Chapters I and III

145213-24-03-01

CE Certiso Kft. (NB 2409) certifies, that the following manufacturer's quality management system concerning the devices and device categories meets the relevant requirements of the regulation.

Manufacturer:

PulseCath B.V.

Registered place of business:	**Nieuwe Stationsstraat 20, 6811 KS, Arnhem, The Netherlands**
Site:	**De Corridor 5, 3621 ZA, Breukelen, The Netherlands**
Single registration number:	**NL-MF-000006626**

The certificate covers the devices listed on the following pages.

Sampling was not applied during the technical documentation assessment. The harmonised standards and the common specification were considered during the assessment referred to below.
This certificate is valid only in case of surveillance audits successfully conducted at least once every 12 months.
In the case of Class III devices, this certificate independently does not authorize the manufacturer to use the CE mark on the devices.

This certificate is valid with the following conditions and/or provisions: ---

ID number of the relevant reports: **65-CE-220118, 65-G1-220119**

Issue: 1
Issued: 01 March 2024
First issued: 01 March 2024
Start date of certified status: 01 March 2024

Date of expiry:
28 February 2029

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Dr. Papp Valter
General Manager

CE Certiso Ltd. NB2409 Notified Body

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Devices covered by this certificate:

Identification of the device	EMDN code	Model	Basic UDI-DI	Intended use	Risk class
Catheter-based ventricular circulatory support devices and accessories	C019001 Aortic counterpulsation catheters	iVAC 2L	87179530372 iVACEG	The iVAC 2L is intended for use in patients with impaired left ventricular function, which requires left ventricular mechanical circulatory support for up to 24 hours. It is intended to be used together with an IABP driver. Indications: A cardiologist and or cardiac surgeon will determine if support with the iVAC 2L is the appropriate option. This is based on one or more of the following clinical and/or anatomical criteria. Clinical criteria: • Acute coronary syndromes (ACS) • Chronic kidney disease • Diabetes mellitus • Hemodynamic instability • Left ventricular ejection fraction (LVEF) of <40% • Previous cardiac surgery Anatomical criteria: • Diffuse CAD • Last patent conduit • Multivessel disease • Severe coronary total occlusion • Severely calcified lesions needing rotational atherectomy • Unprotected left main coronary disease involving bifurcation	III

Certificate revision history:

Issue	Date of issue	Description of changes
1	01.03.2024	Issued.
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