EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Regulation (EU) 2017/745 on Medical devices
Annex IX Chapters II 4

145214-24-03-01

CE Certiso Kft. (NB 2409) certifies, that the following manufacturer's technical documentations concerning the devices
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.

For placing devices on this market this certificate is valid only with the **145213-24-03-01** ID number quality management system certificate, and in case of surveillance audits successfully conducted at least once every 12 months.

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

This certificate is based on the assessment of the **Technical Documentation iVAC 2L_REV4, 2024-02-02** technical documentation. The performed examinations and tests according to Annex XII point 10 are available upon request.
ID number and date of the technical documentation assessment report:
65-G1-220119; 20 February 2024

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 Cardiocirculatory System Devices/Aortic Conterpulsation Catheters	iVAC 2L	87179530372 iVACEG	The iVAC 2L is intended for use in patients with impaired left ventricular function, which require 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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