

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:
Single registration
number:

De Corridor 5, 3621 ZA, Breukelen, The Netherlands

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: --

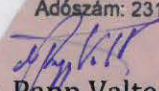
This certificate is based on the assessment of the **Technical Documentation iVAC 2L_REV4, 2024-02-02** technical documentation. The performed examinations and tests according to Annex XII point 10 are available upon request.

ID number and date of the technical documentation assessment report:
65-G1-220119; 20 February 2024

Issue: 2
Issued: 27 May 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



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Devices covered by this certificate:

Identification of the device	EMDN code	Model/ Type	Basic UDI-DI	Intended use	Risk class
Catheter based ventricular circulatory support devices and accessories	C019001 Cardiocirculatory System Devices/Aortic Conterpulsation Catheters	iVAC 2L/ LV17	87179530372 iVACEG	<p>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.</p> <p>It is intended to be used together with an IABP driver.</p> <p>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.</p> <p>Clinical criteria:</p> <ul style="list-style-type: none"> • Acute coronary syndromes (ACS) • Chronic kidney disease • Diabetes mellitus • Hemodynamic instability • Left ventricular ejection fraction (LVEF) of <40% • Previous cardiac surgery <p>Anatomical criteria:</p> <ul style="list-style-type: none"> • 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.
2	27.05.2024	Change of registered place of business.

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