

**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 assessments of the **Technical Documentation iVAC 2L\_REV4, 2024-02-02 (LV17) and Technical Documentation: TD iVAC 2L LV17 and LV16\_REV4, 2025-07-01 LV16)** technical documentations. The performed examinations and tests according to Annex XII point 10 are available upon request. ID number and date of the technical documentation assessment reports: **65-G1-220119; 20 February 2024 (LV17) and 65-G2-240722; 04 August 2025 (LV16)**

Issue: 3

Issued: 12 August 2025

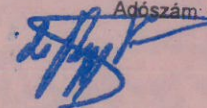
First issued: 01 March 2024

Start date of certified status: 01 March 2024 (LV17)  
12 August 2025 (LV16)

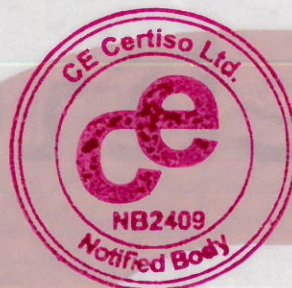
Date of expiry:

**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



**145214-24-03-01**

Devices covered by this certificate:

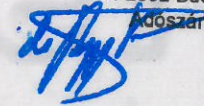
Identification of the device	EMDN code	Model/ Type	Basic UDI-DI	Intended use	Risk class
Catheter based ventricular circulatory support devices and accessories	C019001 Cardiocirculatory System Devices/Aortic Conterpulsation Catheters	iVAC 2L/ LV17 and LV16	87179530372 iVACEG	The iVAC 2L is intended for 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.	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.
3	12.08.2025	Add new model LV16

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