

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:

De Corridor 5, 3621 ZA, Breukelen, The Netherlands

Single registration
number:

NL-MF-000006626

The certificate covers the devices listed on the following pages.

The device(s) covered by this certificate have been assessed by the notified body in accordance with the applicable conformity assessment procedure as set out in the Regulation, with a positive outcome. Details on the device(s) covered by this certificate are provided on the following page(s).

For the purpose of placing on the market the device covered by this certificate, another certificate issued in accordance with the provisions of the Regulation (EU) 2017/745 is required.

The validity of the certificate is conditional upon: --

Issue: 4

Issued: 17 June 2026

First issued: 01 March 2024

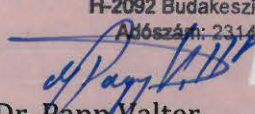
Start date of certified status: 01 March 2024 (LV17)
12 August 2025 (LV16)

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



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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 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
4	17.06.2026	Supplemented - 65-CN-251218

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