

145213-24-03-01

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

Issue: 3
Issued: 12 August 2025

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

[Signature]
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