

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

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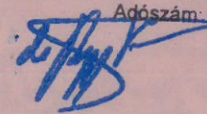
Start date of certified status: 01 March 2024 (LV17)

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

