EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Regulation (EU) 2017/745 on Medical devices
Annex IX Chapters II 4

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.

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)

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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

CE Certiso Ltd. NB2409 Notified Body

Dr. Papp Valter
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