EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 on Medical devices
Annex IX Chapters I and III

145213-24-03-01

CE Certiso Kft. (NB 2409) certifies, that the following manufacturer's quality management system concerning the devices and device categories 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.

Sampling was not applied during the technical documentation assessment. The harmonised standards and the common specification were considered during the assessment referred to below.
This certificate is valid only in case of surveillance audits successfully conducted at least once every 12 months.
In the case of Class III devices, this certificate independently does not authorize the manufacturer to use the CE mark on the devices.

This certificate is valid with the following conditions and/or provisions: ---

ID number of the relevant reports: **65-CE-220118, 65-G1-220119, 65-G2-240722**

Issue: 3
Issued: 12 August 2025
First issued: 01 March 2024
Start date of certified status: 01 March 2024

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

CE Certiso Ltd. NB2409 Notified Body