

Number: 2245542TD02

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Phenox Ltd

Kamrick Court, Ballybrit Business Park, Ballybrit

H91 XY38 Galway

Ireland

SRN ID.: IE-MF-000011333

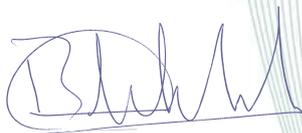
DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2196246CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager

First Issued: **12 December 2024**

Date: **12 December 2024**

Expiry date: **1 December 2029**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s):

Class III				
Basic UDI-DI: 539153091pHLOFAMILY57	<i>Intended Purpose: Esperance pHLO AC is a catheter intended for aspiration in neurovascular vessels as a standalone device or in conjunction with a compatible retrieval device, combining aspiration and mechanical thrombectomy. It can also be used to facilitate the introduction of other suitable devices as well as diagnostic and therapeutic agents subject to use by their IFUs.</i>			
Device Name: Esperance pHLO Aspiration Catheter Type: C0104020207 – Peripheral Thrombectomy and Thromboaspiration Systems				
Models: <table border="1"><tr><td>PHLO-AC-71-125-02</td><td>pHLO Aspiration Catheter 125cm</td></tr><tr><td>PHLO-AC-71-135-02</td><td>pHLO Aspiration Catheter 135cm</td></tr></table>		PHLO-AC-71-125-02	pHLO Aspiration Catheter 125cm	PHLO-AC-71-135-02
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Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	12 December 2024	2196246CN15	First issue
1			
2			

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