EU MDR DECLARATION OF CONFORMITY

Medical Devices Regulation MDR 2017/745

Manufacturer:	*phenox Limited*
Address:	*Kamrick Court,* *Ballybrit Business Park,* *Ballybrit,* *H91 XY38* *Galway, Ireland*
Single Registration Number (SRN):	*IE-MF-000011333*
Basic UDI-DI:	*539153091pNOVUSFAMILYYK*
Product Name:	*pNOVUS 21 Microcatheter*
Product Code(s):	*See page 2 for a complete list of codes covered.*
Intended Purpose:	*The pNOVUS 21 Microcatheter is intended to support the stable access of suitable therapeutic or diagnostic devices, i.e. devices compatible with the inner diameter of the microcatheter, and the infusion of therapeutic and diagnostic agents subject to use by their IFU.*
Common Specifications	*N/A*
Classification:	*Class III Medical Device, in conformity with Annex VIII, Rule 6 of the Medical Device Regulation 2017/745*
Conformity Assessment:	*Annex IX (I QMS & II Assessment of Technical Documentation) of the Medical Device Regulation*

Notified Body: *DEKRA Certification B.V*

Notified Body ID No: *0344*

EC Quality Certificate No.: *2245542CE01*

EC Design Certificate No.: *2245542TD01*

Date CE Mark Affixed: *23rd June 2025*

Product codes covered under the scope of this Declaration of Conformity are listed below;

Product Code	Product Description
PNOV-21-160	pNOVUS 21 Microcatheter 160cm
PNOV-21-150	pNOVUS 21 Microcatheter 150cm

This declaration of conformity is issued under the sole responsibility of phenox Ltd. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745. All supporting documentation is retained at the premises of the manufacturer.

On behalf of phenox Limited;

Signature:

Place and date of issue:

Galway,_24th June 2025

Name (Printed):

Emily Dobosz

Function:

Director of Global Regulatory Affairs