

CERTIFICATE

Number: 2261693

The management system of the organization(s) and locations mentioned on the addendum belonging to:

PulmoTech B.V.

Kamerlingh Onnesstraat 5
9351 VD Leek
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

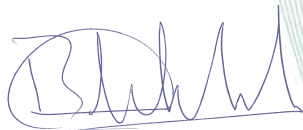
Scope:

Design, development, production and distribution of intelligent Esophageal Pressure Systems intended for patient monitoring during mechanical ventilation and administration of nutrition to patients in the Intensive Care Unit.

Certificate expiry date: 1 June 2026
Certificate effective date: 1 June 2023
Certified since: 1 June 2023

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2261693

The management system of the organization(s) and/or location(s) of:

PulmoTech B.V.

Kamerlingh Onnesstraat 5
9351 VD Leek
The Netherlands

Certified organization(s) and/or locations:

Different scope

PulmoTech BV
(Building of Blue Medical Devices)

Production and distribution of intelligent Esophageal Pressure Systems

Panovenweg 7
5708 HR Helmond
The Netherlands

Addendum expiry date: 1 June 2026

Addendum effective date: 1 June 2023