



CERTIFICATE

EC Certificate No. 1434-MDD-289/2021
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Flotec, Inc.
7625 West New York St.
Indianapolis, Indiana 46214 UNITED STATES

for the design, manufacture and final inspection of medical devices, class: Class IIb

**For use in the area of respiratory/pulmonary medicine and
anesthesiology**

The list of medical devices covered by this certificate is provided in the Annex 1

**complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC**

Validity of the Certificate: from 18.05.2021 to 27.10.2022

The date of issue of the Certificate: 18.05.2021

The date of the first issue of the Certificate: 29.08.2019



Issued under the Contract No. MD-40/2021
Application No: 526/2021
Certificate bears the qualified signature.
Warsaw, 18/05/2021
Module H2/3/4/5
FBM-26-E_9

Vice-President