



# CERTIFICATE

**EC Certificate No. 1434-MDD-181/2021**

**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:

**Scitech Produtos Médicos SA**

**Rua 18, S/N, Quadra Área, Lote 0006, Galpão 01,  
Bairro: Polo Empresarial Goiás – Etapa 1A, Aparecida  
de Goiânia, Goiás, Brasil**

for the design, manufacture and final inspection of  
medical devices, class III

**Embosoft Microspheres**

**Intended use: vascular occlusions**

*The list of medical devices covered by this certificate is provided in the annex to EC Design-examination Certificate No. 1434-MDD-180/2021*

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 2021-04-19 to 2024-05-27

The date of issue of the Certificate: 2021-04-19



Issued under the Contract No. MD-72/2018

Application No: 264/2018

Certificate bears the qualified signature.

Warsaw, 19/04/2021

Module H2/3/4/5

**Vice-President**