



# CERTIFICATE

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**EC Certificate No. 1434-MDD-354/2021**

**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:

**TisgenX Inc.**

**15615 Alton Parkway, Suite 450 Irvine, CA 92618,  
USA**

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

**Non-Active Surgical Patch**

**Bovine Pericardial Tissue Patch**

*The list of medical devices covered by this certificate is provided in the annex 1 to EC Design-examination  
Certificate No. 1434-MDD-353/2021*

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 20.05.2021 to 27.05.2024

The date of issue of the Certificate: 20.05.2021



Issued under the Contract No. MD-35/2020

Application No: 061/2020

Certificate bears the qualified signature.

Warsaw, 20.05.2021

Module H2/3/4/5

**Vice-President**