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POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. M - 99-a/4/2024

This is to certify that:

BIOVICO Sp. z o.o.
ul. Hutnicza 15B, 81-061 Gdynia

(certified locations listed in Annex to the certificate)

is in conformance with

PN-EN ISO 13485:2016-04

in the following scope of activities:

design, development, manufacturing and sale of medical devices: non-active orthopaedic implants, including those containing tissues of animal origin as well as soft implants, injectable hyaluronic acids, devices for the separation of autologous preparations

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above.

This Certificate shall remain valid provided
that above standard are respected by the Organization.

This certificate is valid:

from 06.08.2024 to 29.04.2027

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

Member of Multilateral Recognition Arrangement IAF

Aleksandra Kostmerska
President

Issued under the Contract No. 3813/M/1/2024
Date of certification decision: 06.08.2024
Certificate bears a qualified signature.
Warsaw, 06.08.2024

Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw phone: +48 22 45 46 200, pcbc@pcbc.gov.pl

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POLISH CENTRE FOR
TESTING AND CERTIFICATION

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. M - 99-a/4/2024

This is to certify that the following Locations:

- **BIOVICO Sp. z o.o.**
  ul. Hutnicza 15B, 81-061 Gdynia
  in the following scope of activities:
  design, development, manufacturing and sale of medical devices: non-active orthopaedic implants, including those containing tissues of animal origin as well as soft implants, injectable hyaluronic acids, devices for the separation of autologous preparations

- **BIOVICO Sp. z o.o.**
  ul. Hutnicza 19, 81-061 Gdynia
  in the following scope of activities:
  packaging and sale of medical devices: non-active orthopaedic implants, including those containing tissues of animal origin as well as soft implants, injectable hyaluronic acids

- **BIOVICO Sp. z o.o.**
  ul. Skandynawska 7, 84-120 Władysławowo
  in the following scope of activities:
  manufacturing of medical devices: devices for the separation of autologous preparations

meet the requirements of the standard listed on the certificate.

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
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President

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