

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







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



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.







AC 019

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