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POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. M - 96/4/2024

This is to certify that:

DONGKOOK PHARMACEUTICAL Co., Ltd.
715, Yeongdong-daero, Gangnam-gu, Seoul, 06072, Republic of Korea

(certified locations listed in Annex to the certificate)

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, production, storage and distribution of non active soft tissue implant

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 18.03.2024 to 17.03.2027

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. 3811/M/1/2023
Date of certification decision: 18.03.2024
Certificate bears a qualified signature.
Warsaw, 18.03.2024

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POLISH CENTRE FOR
TESTING AND CERTIFICATION

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. M - 96/4/2024

This is to certify that the following locations:

- **DONGKOOK PHARMACEUTICAL Co., Ltd.**
  715, Yeongdong-daero, Gangnam-gu, Seoul, 06072, Republic of Korea
  in the following scope of activities:
  -
- **DONGKOOK PHARMACEUTICAL Co., Ltd.**
  1103, Jingwang-ro, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, 27809, Republik of Korea
  in the following scope of activities:
  production, storage and distribution of non active soft tissue implant
- **DONGKOOK PHARMACEUTICAL Co., Ltd.**
  33-19, Yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, 27809, Republik of Korea
  in the following scope of activities:
  production, storage and distribution of non active soft tissue implant
- **DONGKOOK PHARMACEUTICAL Co., Ltd.**
  9th Floor, Gyeonggi Bio-Center, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16229, Republik of Korea
  in the following scope of activities:
  design of non active soft tissue implant

meet the requirements of the standard listed on the certificate.

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

Member of Multilateral Recognition Arrangement IAF

Aleksandra Kostmera
President

Issued under the Contract No. 3811/M/1/2023
Date of certification decision: 18.03.2024
Certificate bears a qualified signature.
Warsaw, 18.03.2024

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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