



Certificate of Registration

This is to certify the Quality Management System of:

ALPHAGEM BIO, INC.
4201 Business Center Drive
Fremont, CA 94538

has been assessed and found to be in compliance with the requirements of

ISO 13485:2016

for the following scope:

Designing and Manufacturing Plastic Injection Mold Products that can be used in Medical Fields

ISO 13485:2016

Medical Device Code: Parts & Service

Certificate Number: **SARA-2023-CA-0291-02-A**

Originally Registered:
February 20, 2024

Latest Issue:
February 20, 2024

Certification Cycle:
February 20, 2024 – February 19, 2027

Expiration Date:
February 19, 2027

A large, black, handwritten signature in cursive script, appearing to read "N. A.", positioned above a horizontal line.

President, SARA Registrar



MSCB-194