



Certificate No. CFG-NE1330-6-2024-1

**CERTIFICATE TO FOREIGN GOVERNMENT
FOR DEVICE NOT EXPORTED FROM THE UNITED STATES**

The U.S. Food and Drug Administration (FDA) certifies the following information concerning the device(s) listed below to be shipped from INDIA into foreign countries.

Name of Device(s)

See Attached List

(One Page)

Name of Manufacturer, Address

See Attached List

(One Page)

The device(s) described above (and the manufacturing site(s) which produces it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

It is certified that the above device(s) may be marketed in the United States of America at this time. The manufacturing establishment(s) in which the device(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from July 02, 2024 to July 01, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



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Certificate to Foreign Government for Device not Exported from the United States - Name of Manufacturer

Attachment Page 1 of 1

Name of Owner Operator

Sterile Safequip & Chemicals LLP
Unit 31, Panchratna Industrial Estate, Inside Pirana Gate,
Ghoda Circle, Paldikankaj Ode (V), Off SP Ring Road
Ahmedabad, Gujarat
INDIA 382425

Name of Manufacturer

STERILE SAFEQUIP & CHEMICALS LLP
Unit 31 Panchratna Industrial Estate, Inside Pirana Gate, SP
Ring Road. Village Paldi-Kankaj, Daskroi
Ahmedabad, Gujarat
INDIA 382425

----END OF MANUFACTURER LIST----





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Attachment Page 1 of 1

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 Ahmedabad, Gujarat
 INDIA 382425

Name of Manufacturer

STERILE SAFEQUIP & CHEMICALS LLP
 Unit 31 Panchratna Industrial Estate, Inside Pirana Gate, SP Ring Road. Village Paldi-Kankaj, Daskroi
 Ahmedabad, Gujarat
 INDIA 382425

Name of Product(s)

ZELLESR-10;ZELLESR-20
 ZELLECHEM-PRO;ZELLECHEM-SR
 ZBT-ESR

-----END OF PRODUCT LIST-----

