U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. CFG-NE128-3-2023

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)	**Name of Manufacturer, Address**
See Attached List	See Attached List
(One Page)	(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 April 27, 2023 to April 26, 2025.

For more information about this certificate, please see the FDA's website
<https://www.fda.gov/medical-devices/exporting-medical-devices/devices-not-exported-united-states>.

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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

S.H.Pitkar Orthotools Pvt. Ltd.
EL 32, J Block,
MIDC Bhosari
Pune, Maharashtra
INDIA 411026

Name of Manufacturer

S.H.PITKAR ORTHOTOOLS PVT. LTD.
EL 32, J Block,
MIDC Bhosari
Pune, Maharashtra
INDIA 411026

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

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Pune, Maharashtra
INDIA 411026

Name of Device(s)

Pitkar External Fixation System
Pitkar Locked Plating System
Pitkar External Fixation System - Rail Mechanism
Pitkar Deftfix System
----------END OF DEVICE LIST----------