



**Certificate No. 10342-6-2024-1**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

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 June 26, 2024 to June 25, 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](http://www.access.fda.gov/fecv/CDRH).



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**Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1**

**Name of Owner Operator**

DALE MEDICAL PRODUCTS, INC.  
40 Kenwood Circle  
Suite 7  
Franklin, MA  
USA 02038

**Name of Manufacturer**

DALE MEDICAL PRODUCTS, INC.  
40 Kenwood Circle  
Suite 7  
Franklin, MA  
USA 02038

----END OF MANUFACTURER/DISTRIBUTOR LIST----





**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](http://www.fda.gov)

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**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

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Franklin, MA  
USA 02038

**Name of Manufacturer**

DALE MEDICAL PRODUCTS, INC.  
40 Kenwood Circle  
Suite 7  
Franklin, MA  
USA 02038

**Name of Product(s)**

DALE NASO GASTRIC TUBE HOLDERS 160, 161, 163  
DALE TRACHEOSTOMY TUBE HOLDERS 240, 241, 242, 244  
DALE ENDOTRACHEAL TUBE HOLDERS 270, 273, 280  
DALE FOLEY CATHETER HOLDERS 150, 316, 330  
DALE BENDABLE ARMBOARDS 650, 651, 652, 653  
DALE POST SURGICAL BRAS 701, 702, 703, 704, 705, 706  
DALE ABDOMINAL BINDERS 410, 411, 418, 525, 810, 811, 818, 820, 920  
DALE ACE CONNECTORS 475, 485  
DALE NASAL DRESSING HOLDER 600  
DALE TRANSDUCER HOLDER 620, 622  
DALE IV ARMOR 675

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

