



**Certificate No. 2816-12-2019**

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**

**Name of Distributor**

MEDISPEC, LTD.  
203 Perry Pkwy Ste 6  
Gaithersburg, MD USA 20877

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 December 11, 2019 to December 10, 2021.**





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

**Certificate No. 2816-12-2019**

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

**Name of Distributor**

MEDISPEC, LTD.  
203 Perry Pkwy Ste 6  
Gaithersburg, MD USA 20877

**Name of Product(s)**

ED1000  
Radialspec  
Econolith EM1000  
Econolith E2000  
Econolith E3000  
Orthospec  
Lithospec  
Slimspec  
Urospec

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

