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Locke Lord QuickStudy: ?BIS Introduces License Exception MED ?for Medical Device ?Exports to Russia, Belarus, and Occupied ?Ukraine ?

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Effective April 29, 2024, the U.S. Department of Commerce's Bureau of Industry and Security ("BIS") introduced a new export license exception to allow the export of medical devices to or within Russia, Belarus and the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine. This amendment to the Export Administration Regulations ("EAR") underscores the United States' humanitarian commitment to the people of these nations and geographies.

Dubbed "License Exception MED," this initiative alleviates the need for specific licenses to export critical medical devices. "Medical devices", for the purposes of this BIS license exception, is defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), and includes medical supplies, instruments, equipment, equipped ambulances, institutional washing machines for sterilization, and vehicles with medical testing equipment.

License Exception MED does not authorize exports of covered medical items to restricted parties, including those on the BIS Entity List, Military End User List or persons identified on the Specially Destinated Nationals and Blocked Persons List (the (*i.e.*, the SDN list) maintained by the U.S. Department of the Treasury's Office of Foreign Assets Control.

License Exception MED also introduces the concept of "Know Your Customer" which is intended to prevent exports to production facilities, as defined under the EAR, if there is knowledge or reason to believe that the device is intended for the development or production of items in Russia. License Exception MED includes certain verification requirements to prevent unauthorized use or diversion of the approved medical devices including affirmations of compliance from consignees and/or conducting periodic on-site spot checks. Exporters are also required to comply with recordkeeping requirements under the EAR, including maintaining comprehensive records of transfers and verification activities for a minimum of five years.

For companies with pending license applications for medical device exports to the specified regions identified herein, two viable options are available: (i) continue with the application process, which stands a good chance of approval if License Exception MED criteria are met; or (ii) seek a Return Without Action (*i.e.*, the license application is returned without issuing a license or denying it), which will allow for the company to amend its application and use the License Exception MED.

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Conclusion

This paper is intended as a guide only and is not a substitute for specific legal or ?tax advice. ??Please ????reach out to the ?authors for any specific questions. We expect ?to continue to monitor the ??topics ????addressed in this paper and provide ?future ?client updates when useful.?

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