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Export Controls Alert

April 26, 2024

BIS issues new License Exception MED

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This exception applies to EAR99 medical devices and EAR99 parts, components, accessories, and attachments.

What's the impact?

- The new License Exception MED authorizes the export, (re)export, or transfer (in-country) of EAR99 medical devices and parts, components, accessories, and attachments designated as EAR99 that are exclusively for use in such medical devices.
- US exporters can use this License Exception as soon as Customs issues the license code that needs to be entered into the Electronic Export Information (EEI). Reexporters outside the US do not need to file an EEI and can, therefore, start using the new exemption once it has been formally published on Monday, April 29.

On April 25, 2024, the Department of Commerce's Bureau for Industry and Security (**BIS**) announced that it will amend the EAR to add a new license exception for "medical devices" under § 740.23 (Medical Devices (**MED**)). License Exception MED will authorize the export, (re)export, or transfer (in-country) of medical devices that are classified as EAR99 to or within

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Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine (collectively, the **Covered Destinations**). It equally will authorize the export, (re)export, and in-country transfer of parts, components, accessories, and attachments classified as EAR99 that are exclusively for use in or with such medical devices. This is a significant development since prior to this rule, EAR99 medical devices could not be (re)exported or transferred to the Covered Destinations without a license if they were described in Supplement 6 to Part 746 of the EAR or if their HTS code was listed in Supplement 4 or 5 to Part 746 of the EAR.

The amendment will officially be published (and thereby come into effect) on **Monday, April 29**. US exporters will be able to use MED as soon as US Customs and Border Protection (**US Customs**) issues the complementary License Code that needs to be entered in the EEI. We anticipate that to be May 10 at the latest.

New License Exception MED

License Exception MED will authorize the export, (re)export, or transfer (in-country) of medical devices classified as EAR99 to or within the Covered Destinations. Medical devices that will fall within the scope of MED are those medical devices described in Supplement No. 3 to part 774 – Statements of Understanding under paragraph (a) (Statement of Understanding - medical equipment) and in the definition of "medical device" in § 772.1 of the EAR.

MED will also be available for parts, components, accessories, and attachments designated as EAR99 that are exclusively for use in or with EAR99 medical devices and fulfill all the additional requirements of § 740.23(a)(1)-(2), specifically if:

- The part, component, accessory, or attachment is being exported, (re)exported, or transferred (in-country) solely as a replacement for a broken or nonoperational counterpart, or the export, (re)export, or transfer (in-country) of such replacement parts, components, accessories, and attachments is necessary and ordinarily incident to the proper preventative maintenance of such a medical device; *and*
- The number of replacement parts, components, accessories, and attachments that are exported, (re)exported, transferred (in-country), and stored does not exceed the number of corresponding operational parts, components, accessories, and attachments currently in use in or with the relevant medical devices.

Restrictions to MED

License Exception MED does not overcome any license requirements imposed under § 746.8 or any other EAR license requirement (e.g., those specified under part 744) other than those specified under §§ 746.5, 746.6, or 746.10. For example, any item with an ECCN—regardless of any medical end use—is generally subject to licensing requirements for Belarus and Russia under §

746.8. Additionally, License Exception MED may not be used if the restrictions under § 740.2 apply, for example, if a party is designated on a BIS list.

License Exception MED also cannot be used to help support the Russian industrial base (including the Russian medical device industry) or to enable "proscribed" (i.e., sanctioned) entities or individuals to receive eligible items. Further, MED is not available for any (re)export or transfers (in-country) destined to a production facility (as defined in § 772.1), and when the (re)exporter or transferor has knowledge that the items are intended to "*develop or produce items.*" Knowledge, as defined in § 772.1, includes not only positive knowledge that the circumstance exists or is substantially certain to occur but also an awareness of a high probability of its existence or future occurrence. It is important to note that BIS does not consider the assembly in a hospital or other healthcare facility of a finished medical device completely produced outside of the Covered Destinations for the sole purpose of using that medical device at that facility as a production activity.

Verification procedure and recordkeeping

The use of MED requires (re)exporters and transferors to maintain a system of distribution that ensures that their medical devices are not delivered to "proscribed persons" or entities engaged in the "production" of any product. They are responsible for ensuring that their items are not diverted contrary to the terms and conditions of License Exception MED. This verification may entail obtaining certain information from a consignee (e.g., obtaining affirmations or other documentation from a consignee as part of the compliance program) to ensure that the use and disposition of the medical devices received under License Exception MED meet the required terms and conditions. (Re)exporters and transferors must maintain records of verification for five (5) years and, upon request, provide them to BIS.

Preparing the EEI

US exporters who want to use the new License Exception MED should be aware that, in order to use it, they will need to claim it in the EEI. For this, exporters will have to enter the License Code to claim the exemption that will be issued by the US Customs (not BIS). US Customs generally takes a few days to issue the complementary License Code after the rule comes into effect. We expect that the license code is likely to be issued by May 10 at the latest.

Practical impact

(Re)exporters and transferors of medical devices classified as EAR99 and/or parts, components, accessories, or attachments (classified as EAR99) for such medical devices should thoroughly review whether they are eligible to use the new License Exception MED. This will significantly lighten the administrative and practical burden imposed by BIS on such (re)exports and

transfers, especially because before this amendment—contrary to the Iran embargo—EAR99 medical devices were not eligible for a license exception for Russia or the other Covered Destinations. Before claiming License Exception MED, US exporters should, as noted above, ensure that the appropriate license code was issued by US Customs and enter the code accordingly in their EEI. Further, they need to ensure that they meet all verification requirements and keep records of the (re)export or transfer, including the verification documentation, for five years.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

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