BUREAU OF INDUSTRY AND SECURITY
FREQUENTLY ASKED QUESTIONS
LICENSE EXCEPTION MEDICAL DEVICES
CURRENT AS OF APRIL 25, 2024

Q1: What is the purpose of License Exception Medical Devices (MED) (§ 740.23 of the EAR)?

A1: The purpose of this license exception is to authorize (subject to certain terms and conditions) certain exports, reexports, and transfers (in-country) that BIS generally has been approving under the license application review policies set forth in §§ 746.5, 746.6, and 746.10 of the Export Administration Regulations (EAR). License Exception MED also authorizes "parts," "components," "accessories," and "attachments" designated as EAR99 that are exclusively for use in or with "medical devices" designated as EAR99.

Q2: What countries and areas are impacted by this rule?

A2: License Exception MED is only available to authorize exports, reexports, and transfers (in-country) to or within Russia, Belarus, the temporarily occupied Crimea region of Ukraine, and the covered regions of Ukraine (as defined in § 746.6(d) of the EAR and EO 14065).

Q3: What is the definition of "medical devices" and their "parts," "components," "accessories," and "attachments?"

A3: See paragraph (a) of Supplement No. 3 to Part 774 of the EAR (Statement of Understanding - medical equipment) for guidance on classifying medical equipment. The definition of "medical device" is provided in § 772.1 of the EAR, as well as definitions of the terms "parts," "components," "accessories," and "attachments" designated as EAR99 that are exclusively for use in or with "medical devices" designated as EAR99." Exporters, reexporters, or transferors that need assistance in classifying their items to determine whether they are designated as EAR99 may submit classification requests to BIS using the Simplified Network Application Process (SNAP-R) available on the BIS website at https://snapr.bis.doc.gov/snapr/

Q4: May exporters, reexporters, or transferors use License Exception MED to export, reexport, or transfer (in-country) medical devices or their "parts," "components," "accessories," or "attachments" to the Russian or Belarusian military without a license?

A4: No. You may not use License Exception MED if you have "knowledge" that any item "subject to the EAR" is intended entirely, or in part, for a Russian or Belarussian 'military end user' (§744.21 (g)) or may be used to support a 'military end use' (§744.21 (f)) within Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine. Russian and Belarusian 'military end users' include those entities on the Entity List (Supplement No. 4 to part 744) with a Footnote 3 designation. Note that there are also restrictions for certain

foreign-produced items applicable to Russian and Belarusian "military end users." (*See* §§ 734.9(g) and § 746.8(a)(3) of the EAR)

Q5: May License Exception MED be used to export, reexport, or transfer (in-country) medical devices or their "parts," "components," "accessories," or "attachments" to commercial entities and enterprises not owned or operated by the Russian government that sell medical devices to individual Russian customers?

A5: Yes, but commercial entities and enterprises, including retail outlets, distributors, etc., must conduct due diligence to ensure that items eligible for License Exception MED are not re-sold to other Russian parties that are not themselves eligible. These commercial entities and enterprises may not be an entity excluded from receiving items under § 740.23(b)(1) or (2) or engaged in an prohibited "production" end use under § 740.23(b)(3) and the items must only be destined for an eligible end use authorized under License Exception MED.

Q6: Under what circumstances may I use License Exception MED to export, reexport, or transfer (in-country) EAR99 medical devices and/or their "parts," "components," "accessories," and/or "attachments" without a license?

A6: License Exception MED may be used only for the export, reexport, or transfer (in-country) of EAR99 medical devices and/or their "parts," "components," "accessories," and/or "attachments" to civilian medical end-users in Russian, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine. In addition, License Exception may not be used for exports, reexports, or transfers (in-country) that are destined to:

1. Russian or Belarusian "military end users," any Entity List party; any "production" "facility" in Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine; or any other party that will use the items for "development" or "production" of items;
2. Medical facilities that are owned or operating under the auspices of the Russian or Belarusian Ministries of Defense;
3. Any "proscribed person," including but not limited to 'military end users' (see §§ 744.17(e) and 744.21(g)) or in situations in which an entity on the Entity List in supplement no. 4 to part 744 or on the Military End-User (MEU) List) is a party to the transaction as described in § 748.5(c) through (f) of the EAR.

Q.7: Are the verification procedures identified under § 740.23(c) and the examples of acceptable verification methods provided illustrative to highlight the types of procedures that exporters, reexporters, and transfers may adopt to implement their required verification procedures?

A:7: The methods identified are illustrative. Section 740.23(c) imposes a requirement on exporters, reexporters, and transferors to maintain a system of distribution that ensures that "medical devices" are not delivered to "proscribed persons" or entities engaged in the "production" of any product. Exporters, reexporters, and transferors are responsible for ensuring that the items being exported, reexported, or transferred (in-country) are not diverted contrary to

the terms and conditions of License Exception MED. The paragraph (c) text specifies that the verification of the effectiveness of the distribution system may entail obtaining certain information from a consignee (*e.g.*, obtaining affirmations or other documentation from a consignee as part of an exporter, reexporter, or transferor's compliance program) for ensuring that the use and disposition of "medical devices" received under License Exception MED meet the required terms and conditions. Paragraph (c) also provides another illustrative example for how the verification of the effectiveness of the distribution system may be confirmed by the exporter, reexporter, or transferor by conducting periodic on-site spot checks. License Exception MED includes criteria in a parenthetical phrase that follows the phrase 'or performing periodic on-site spot-checks' to provide illustrative examples of the verification methods that may be adopted to ensure the effectiveness of the distribution system when an exporter, reexporter, or transferor decides to use conducting periodic on-site spot checks. This parenthetical phrase specifies that a verification system may include periodic on-site spot-checks in Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine, by the exporter, reexporter, or transferor; an internationally accredited auditing firm; or by an internationally recognized non-governmental humanitarian organization.

Best Practices Checklist for Using License Exception MED

- Have you determined that the "medical device" or "parts," components," "accessories," or "attachments" are "subject to the EAR" and designated as EA99?
    - License Exception MED is only available for "medical devices" designated as EAR99 or for "parts," components," "accessories," or "attachments" that are "subject to the EAR" that are exclusively for use in or with "medical devices" designated as EAR99. In addition, the EAR99 designated "parts," components," "accessories," or "attachments" must be exclusively for use in or with "medical devices" designated as EAR99 in order to be authorized under License Exception MED.

- Have you determined that the "medical devices" or "parts," components," "accessories," or "attachments" requires a license to Russia, Belarus, the temporarily occupied Crimea region of Ukraine, or the covered regions of Ukraine?
    - License Exception MED may only overcome license requirements imposed under §§ 746.5, 746.6, and 746.10.

- Have you reviewed the general restrictions on the use of EAR license exceptions under § 740.2?
    - License Exception MED is not available if the export, reexport, or transfer (in-country) is otherwise restricted under § 740.2.

- Have you reviewed all of the applicable terms and conditions of License Exception MED under § 740.23 and determined you can comply with all of these applicable terms and conditions, including adopting a verification process as specified under § 740.23(c)?

- BIS allows for flexibility in how an exporter, reexporter, or transferor implements a verification process under License Exception MED and includes illustrative examples under § 740.23(c) to provide guidance for developing a verification system.

• Have you set up a process to comply with the recordkeeping and verification requirements identified in §§ 762.2 and 740.23(c) and (d) of the EAR, which require exporters, reexporters, and transferors to maintain records of records they generate as part of the verification procedures that they chose to implement to meet the verification requirements identified under 740.23(c), as specified in paragraph (d), for 5 five years, and, upon request, to provide these records to BIS, or any other official of the United States designated by BIS, for review?

• Are the item quantities scoped to what would be used over the period of 12 to 24 months, to avoid potential stockpiling?

• Have you initiated a process to ensure that the items are not diverted to end uses or end users that are contrary to the terms and conditions of License Exception MED?

• Have you conducted and documented your due diligence efforts to minimize the risk of diversion to unauthorized end users/end uses?