Medical Device Excise Tax - IRC 4191

Frequently Asked Questions

Q1. What is the medical device excise tax?
A1. Section 4191 of the Internal Revenue Code imposes an excise tax on the sale of certain medical devices by the manufacturer or importer of the device.

Q2. When does the tax go into effect?
A2. The tax applies to sales of taxable medical devices after December 31, 2012.

Q3. How much is the tax?
A3. The tax is 2.3 percent of the sale price of the taxable medical device. See Chapter 5 of IRS Publication 510, Excise Taxes, and Notice 2012-77 for additional information on the determination of sale price.

Q4. Who is responsible for reporting and paying the medical device excise tax?
A4. Generally, the manufacturer or importer of a taxable medical device is responsible for filing Form 720, Quarterly Federal Excise Tax Return, and paying the tax to the IRS.

Q5. Will individual consumers be subject to any reporting or recordkeeping requirements?
A5. Generally, no action is required by individual consumers. Because the tax is imposed upon the sale of a taxable medical device by the manufacturer or importer, the manufacturer or importer is responsible for reporting and paying the tax.

Q6. Who is the manufacturer for purposes of the medical device excise tax?
A6. Generally, with regard to the medical device excise tax, the manufacturer is the person who produces a taxable medical device from scrap, salvage or junk material, or from new or raw material, by processing, manipulating or changing the form of a device or by combining or assembling two or more devices.

Q7. Who is the importer for purposes of the medical device excise tax?
A7. Generally, with regard to the medical device excise tax, the importer of a taxable medical device is the person who brings the device into the United States from a source outside the United States, or withdraws the device from a customs-bonded warehouse for sale or use in the United States.

Q8. What is the tax treatment of convenience kits?
A8. Notice 2012-77 provides interim guidance on the tax treatment of convenience kits. Under the interim guidance, a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, but the sale of the convenience kit by the kit producer will not be subject to tax. Special rules apply to imported kits.

For purposes of the notice, a convenience kit is a set of two or more devices within the meaning of § 201(h) of the Federal Food, Drug, and Cosmetic Act that is enclosed in a single package, such as a bag, tray, or box, for the convenience of a health care professional or the end user.

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Q9. What form will be used to report the medical device excise tax?
A9. The medical device excise tax is a manufacturers excise tax. Like other manufacturers excise taxes, the medical device excise tax is reported on Form 720. See Chapters 11 and 12 of IRS Publication 510 for additional information on filing, deposits, and payments.

Q10. When is the Form 720 due?
A10. Form 720 is filed quarterly. The first return to report the medical device excise tax will be due on April 30, 2013, for the quarterly period including January, February, and March 2013. Quarterly return due dates are as follows:

For the months:	Due by:
Jan., Feb., Mar.	April 30
Apr., May, Jun.	July 31
Jul., Aug., Sep.	Oct. 31
Oct., Nov., Dec.	Jan. 31

Q11. Are tax deposits required for the medical device excise tax?
A11. Yes. Semi-monthly deposits will generally be required if tax liability exceeds $2,500 for the quarter. The first deposit of the medical device excise tax, covering the first 15 days of January 2013, will be due on January 29, 2013. Notice 2012-77 provides transition relief from deposit penalties during the first three calendar quarters of 2013. For details on deposit requirements, see the Instructions to Form 720 and Chapter 12 of IRS Publication 510.

Q12. Should an entity that is disregarded for income tax purposes file Form 720 in the disregarded entity's name or the owner's name?
A12. An entity that is disregarded as an entity separate from its owner for income tax purposes is treated as a separate entity for excise tax purposes. Therefore, the entity, and not the disregarded entity's owner, is responsible for filing Form 720 and paying of the tax.

Q13. Has the IRS issued guidance on the medical device excise tax?
A13. Yes. The IRS and the Treasury Department issued final regulations on December 5, 2012. The IRS and the Treasury Department issued Notice 2012-77 on December 5, 2012, to provide interim guidance on certain issues related to the medical device excise tax.

Q14. What is a taxable medical device?
A14. In general, a taxable medical device is a device that is listed as a device with the Food and Drug Administration under section 510(j) of the Federal Food, Drug, and

Cosmetic Act and 21 CFR part 807, unless the device falls within an exemption from the tax, such as the retail exemption.

Q15. Are there any exemptions to the medical device excise tax?
A15. Yes. There are specific statutory exemptions for eyeglasses, contact lenses, and hearing aids. There is also an exemption for other devices that are of a type that are generally purchased by the general public at retail for individual use (the retail exemption).

Q16. How does a manufacturer determine if a particular type of device qualifies for the retail exemption?
A16. The regulations provide a facts and circumstances approach to determine whether a type of device meets the retail exemption. The regulations enumerate several factors that are relevant, but there may be relevant factors in addition to those enumerated in the regulations. The determination is based on the overall balance of factors relevant to a particular type of device. No one factor is determinative. See § 48.4191-2(b)(2) of the regulations for more information about the retail exemption. The regulations also provide a safe harbor for certain devices that will be considered to be of a type that falls within the retail exemption. See Q&A 18.

Q17. Do the regulations illustrate how the retail exemption facts and circumstances test should be applied?
A17. Yes. The regulations include examples that apply the facts and circumstances test to several types of medical devices. Based on the totality of the circumstances presented in the examples, the examples conclude that non-sterile absorbent tipped applicators, adhesive bandages, snake bite suction kits, denture adhesives, mechanical and powered wheelchairs, portable oxygen concentrators, and therapeutic AC powered adjustable home use beds are devices that fall within the retail exemption. Based on the totality of the circumstances presented in the examples, the examples also conclude that mobile x-ray systems, nonabsorbable silk sutures, and nuclear magnetic resonance imaging systems are not devices that fall within the retail exemption.

Q18. Is there a retail exemption safe harbor?
A18. Yes. The regulations identify certain categories of devices that qualify for the retail exemption so that manufacturers and importers do not have to apply the facts and circumstances test. Those categories are set forth in a safe harbor provision in § 48.4191-2(b)(2)(iii) of the regulations.

Q19. Are there any circumstances under which a taxable medical device can be sold tax-free?
A19. Yes. A manufacturer or importer of a taxable medical device may, in certain circumstances, sell a taxable medical device tax-free for use by the purchaser for further manufacture (or for resale by the purchaser to a second purchaser for further manufacture), or for export (or for resale for export). To make a tax-free sale for further manufacture or export, both parties to the sale must be registered with the IRS. Form 637, Application for Registration for Certain Excise Tax Activities, is used for the registration process. For more information on the Form 637 registration process, see the 637 Registration Program at IRS.gov.

Q20. I'm not familiar with manufacturers excise taxes. Where can I learn more?
A20. For more information about manufacturers excise taxes in general, see Chapter 5 of IRS Publication 510.