

§ 4191. Medical devices**(a) In general**

There is hereby imposed on the sale of any taxable medical device by the manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which so sold.

(b) Taxable medical device

For purposes of this section—

(1) In general

The term “taxable medical device” means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.

(2) Exemptions

Such term shall not include—

- (A) eyeglasses,
- (B) contact lenses,
- (C) hearing aids, and
- (D) any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.

(Added Pub. L. 111-152, title I, §1405(a)(1), Mar. 30, 2010, 124 Stat. 1064.)

REFERENCES IN TEXT

Section 201(h) of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(1), is classified to section 321(h) of Title 21, Food and Drugs.

PRIOR PROVISIONS

For prior sections 4191, 4192, 4201, and 4211, see Prior Provisions note set out preceding this section.

EFFECTIVE DATE

Pub. L. 111-152, title I, §1405(c), Mar. 30, 2010, 124 Stat. 1065, provided that: “The amendments made by this section [enacting this section and amending sections 4221 and 6416 of this title] shall apply to sales after December 31, 2012.”

Subchapter F—Special Provisions Applicable to Manufacturers Tax

Sec.	
4216.	Definition of price.
4217.	Leases.
4218.	Use by manufacturer or importer considered sale.
4219.	Application of tax in case of sales by other than manufacturer or importer.
[4220 to 4225. Repealed.]	

AMENDMENTS

1958—Pub. L. 85-859, title I, §§117(d), 119(b)(3), Sept. 2, 1958, 72 Stat. 1281, 1286, substituted “Leases” for “Lease considered sale” in item 4217, and struck out items 4220 to 4225.

1956—Act June 29, 1956, ch. 462, title II, §207(b), 70 Stat. 392, added item 4226 and redesignated former item 4226 as 4227.

§ 4216. Definition of price**(a) Containers, packing and transportation charges.**

In determining, for the purposes of this chapter, the price for which an article is sold, there shall be included any charge for coverings and containers of whatever nature, and any charge incident to placing the article in condition

packed ready for shipment, but there shall be excluded the amount of tax imposed by this chapter, whether or not stated as a separate charge. A transportation, delivery, insurance, installation, or other charge (not required by the foregoing sentence to be included) shall be excluded from the price only if the amount thereof is established to the satisfaction of the Secretary in accordance with the regulations.

(b) Constructive sale price**(1) In general**

If an article is—

- (A) sold at retail,
- (B) sold on consignment, or
- (C) sold (otherwise than through an arm’s length transaction) at less than the fair market price,

the tax under this chapter shall (if based on the price for which the article is sold) be computed on the price for which such articles are sold, in the ordinary course of trade, by manufacturers or producers thereof, as determined by the Secretary. In the case of an article sold at retail, the computation under the preceding sentence shall be on whichever of the following prices is the lower: (i) the price for which such article is sold, or (ii) the highest price for which such articles are sold to wholesale distributors, in the ordinary course of trade, by manufacturers or producers thereof, as determined by the Secretary. This paragraph shall not apply if paragraph (2) applies.

(2) Special rule

If an article is sold at retail or to a retailer, and if—

- (A) the manufacturer, producer, or importer of such article regularly sells such articles at retail or to retailers, as the case may be,
- (B) the manufacturer, producer, or importer of such article regularly sells such articles to one or more wholesale distributors in arm’s length transactions and he establishes that his prices in such cases are determined without regard to any tax benefit under this paragraph, and
- (C) the transaction is an arm’s length transaction,

the tax under this chapter shall (if based on the price for which the article is sold) be computed on whichever of the following prices is the lower: (i) the price for which such article is sold, or (ii) the highest price for which such articles are sold by such manufacturer, producer, or importer to wholesale distributors (other than special dealers).

(3) Constructive sale price in case of certain articles

Except as provided in paragraph (4), for purposes of paragraph (1), if—

- (A) the manufacturer, producer, or importer of an article regularly sells such article to a distributor which is a member of the same affiliated group of corporations (as defined in section 1504(a)) as the manufacturer, producer, or importer, and
- (B) such distributor regularly sells such article to one or more independent retailers,