

IRS releases final regulations and interim guidance on medical device excise tax

Guidance impacts manufacturers, producers and importers of medical devices

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On 7 December, the Treasury Department and the Internal Revenue Service published [final regulations](#) and additional interim guidance under Internal Revenue Code section 4191 relating to the medical device excise tax (MDET) that was enacted as part of the Health Care and Education Reconciliation Act of 2010, in conjunction with the Patient Protection and Affordable Care Act.

Effective January 1 2013, section 4191 imposes a 2.3% excise tax on sales of certain medical devices by the manufacturer, producer, or importer of the device. The final regulations generally adopt the guidance in the proposed regulations issued in February of this year, but provide greater certainty with respect to the types of devices that are subject to the MDET and clarification on the retail and other exemptions.

The final regulations do not address certain issues that the IRS and the Treasury continue to evaluate. As a result, the Treasury and the IRS simultaneously issued [Notice 2012-77](#) and a [frequently asked questions](#) document to provide interim guidance on some of the more significant issues facing the medical device industry as it readies itself for the MDET.

A detailed [tax alert](#) explaining the final regulations and the interim guidance is available from Deloitte Tax.

If you have any questions on the above, do not hesitate to contact myself or one of my tax colleagues on our Life Sciences team.

Kind regards,

Lorraine Griffin

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