



MDETS - MEDICAL DEVICE EXCISE TAX

DMA's Medical Device Excise Tax Solution (MDETS) provides users with a centralized tax management and reporting solution for the Medical Device Excise Tax. The solution presents users with a web-based interface for managing FDA-listed medical devices, data extraction from accounting systems, constructive sale pricing rules, exemption management, reporting, adjustments, and payment processing.

Using MDETS, reporting sales data, filing returns and creating an audit trail become automated processes. Record retention is electronic and business reports may be customized. The software automates the importing and processing of data, memorializes sales and taxation data, and creates output files for loading into the client's ERP for accounting purposes. MDETS can be administered locally and offers system security functionality to ensure appropriate personnel can edit or view MDETS data.

Problem: Determining What Constitutes a Taxable Medical Device

The FDA requires you to register medical devices so they can be maintained and regulated within the FDA website. If it is determined that an item is a medical device, it is subject to the Medical Device Excise Tax (provided there are no exclusions/exceptions).

Identification of taxable medical devices begins with determining your manufactured or imported products that are listed as medical devices for human consumption. This is the first step in determining which of these FDA-listed medical devices creates a tax liability. There are numerous statutory, regulatory, and administrative exceptions and exemptions to apply. Additionally, there are various case-and-circumstances applications which might result in exemption.

Solution: FDA-Listed Medical Device Management

Manufacturers and importers regularly maintain an inventory of FDA-listed medical devices which are coded within their ERP system. MDETS identifies this inventory as the initial step of compliance. As the listed medical devices are withdrawn from inventory (either due to sale or for internal use or consumption), this software allows for further identification of tax exceptions and exemptions, and the corresponding reason. Only those medical devices subject to tax remain.

Problem: Extracting Taxable Transactions from the Accounting System

Between systems, it is important to create and maintain efficient pathways for extracting and processing data and for returning processed data to its source.

Solution: MDETS Import Management

MDETS imports data from a multitude of file formats (e.g. CSV, XLS, XLXS, TXT, etc.) so that data flows may be maintained with limited burden on existing systems. MDETS also allows clients to map any file layout within MDETS using the Flexi-Import tool, eliminating the need to modify the source format of the extract.



Problem: *Determining the Correct Sale Price for Tax Calculation*

It is important for any Medical Device Excise Tax software to apply IRS sale pricing rules (actual or constructive) for the correct calculation of the tax.

Solution: *MDETS Sale Pricing Rules Management*

MDETS' functionality allows for the application of IRS sale pricing rules based on individual client circumstances. Following are examples of different sale pricing rules that can be utilized within MDETS:

- Fixed actual and constructive sale pricing (from accounting system or within MDETS)
- Basis Percentage
- Present Value
- Capped Transaction

Problem: *Identifying Sales for Further Manufacture and Exportation Exemptions*

While IRC §4221(a)(1) and (2) provide exemptions to Medical Device Excise Tax taxpayers making such sales, the burden falls on the taxpayer to prove the purchaser is representing the propriety of the exemption. This proof must be maintained and available upon audit to support the exemption claimed.

Solution: *Exemption Management*

MDETS has central exemption management functionality where clients can enter exemptions for fact patterns (specific limiters). The system has the ability to store documentation needed during an audit to prove the exemption. Reporting on transactions exempt from Medical Device Excise Tax is also available with MDETS.

Problem: *Running Reports for Data Validation*

It is important to be able to reconcile and validate the Medical Device Excise Tax calculations prior to making payments to the IRS.

Solution: *Reporting Management*

The reporting feature within MDETS allows for the creation of custom reports. Reports can be detailed or summaries depending on the information needed by the client's tax department. Reports can be set up to run automatically, ensuring that the proper resources receive the data in a timely fashion (without having to access the MDETS system).

Problem: *Making Needed Adjustments*

Instances will occur when reporting errors or subsequent price adjustments will necessitate changes to the tax base and calculations.

Solution: *Adjustment Management*

MDETS allows clients to make "lump sum" adjustments to the Medical Device Excise Tax calculations that can be returned to the accounting system for accurate accountancy.