Factsheet 2017

Global Regulatory Intelligence on Medical Devices & IVDs—When and Where You Need It

When You Need to **Compare Requirements Across Countries**

Excel Spreadsheets: Tarius Cross-Country Tables (CCTs) let you view a wide range of operational details, country by country, to compare, contrast, and better understand how to leverage information across regulatory agencies. For Medical Devices, Tarius provides six CCTs across all countries and regions covering:

1. **Marketing/Clearance Application, including Packaging & Labeling:** Types of Applications, consultations with authorities, format requirements, language, electronic gateways, expected review timelines, renewals, pre-inspections. For Packaging/labeling: Registration, languages, control numbers, symbol use, labeling for clinical use, sterile devices.

2. **Device Classification:** Class names, determinations, exemptions, premarket requirements, databases.

3. **Safety:** Adverse event reporting during CT and Post-market; including periodic reporting, device tracking, and recalls.

4. **Fees:** Types of fees, current amounts, currency, payment options and addresses, exemptions, penalties for non-payment.

5. **Import/Export:** For import: general requirements, certificates required, labeling, documentation, import for investigational use, and more.
For export: general requirements, certificates required, labeling, documentation, export for investigational use.

6. **IVDs:** Specific requirements for IVDs including registration procedures, notified bodies, labeling and trade organizations.

In total, the medical device tables include 300 data cells per country.

When You Need to **Retain and Retrieve Company Data**

Local knowledge from your affiliates, distributors and consultants can be difficult to find and keep up to date. **The Tarius Editor** now allows you to organize your proprietary company data into the Cross-Country Tables (CCTs) for easy retrieval!

The customizable data sections have full CCT functionality, including active links to documents and websites as well as the ability to export in Excel format.

Using the **Tarius Document Uploader**, you may also upload proprietary company documents in Word or PDF format. Users will retrieve the company documents via full-text searching as well as via navigation to company-specific menus. Newly uploaded company documents may be included in the personalized newsletters.

Your company data are stored in a secure space, visible only to your colleagues.

When You Need to **Go In-Depth**

Local Regulatory Expertise: Use Tarius Expert Summaries to guide you through local submission procedures and practices. More than **20 expert summaries** per country describe the national regulatory setup for medical device classification, quality systems requirements, clinical trials, marketing approval, establishment registration, packaging and labeling, reporting, recalls, advertising, device tracking, inspection of manufacturing sites, sale to consumers, data protection, import/export, pricing and reimbursement, enforcement, and more. Every expert summary is created exclusively for Tarius by our global network of trusted, independent experts.

Tarius A/S · Klerkegade 19 · 1308 Copenhagen · Denmark · www.tarius.com · sales@tarius.com · +45 7211 2124

TARIUS

When You Need
Global Coverage

Continuously Updated Information: Tarius monitors more than 250 government websites and official journals daily in order to bring you the most up-to-date draft and final versions of relevant acts, regulations, directives, codes, decisions, policy papers, guidelines, warning letters, safety alerts, recalls, press releases, forms, and more. Plus Tarius archives all historic versions for easy retrieval and comparison.

Translations of non-English documents enable you to better understand the implications for your company. Tarius provides machine-translated versions at a fixed annual cost.

Tarius notifies you when ISO and ASTM publish new versions of your selection of standards. Monitoring relevant ISO and ASTM standards on request, Tarius can deliver a customizable news service to all healthcare companies.

Tarius includes guidelines, technical reports and policy papers from the following organizations, relevant for medical devices:

- EDMA
- Eucomed
- IMDRF
- MedTech Europe
- WHO

Make "My Tarius" Your Personal Dashboard

When You Need to
Stay Up-to-Date

Personalized Newsletters
Sign up to receive a customized newsletter from Tarius featuring only those document categories relevant to your business.

Alerts on Document Changes
Create personalized alerts to receive notifications about new versions and approaching deadlines for submitting comments.

Alerts on Saved Searches
Get notified when new documents are available that match your search queries.

Tarius Administrators may define newsletters and alerts tailored to project needs on behalf of team members

When You Need to
Find Information Fast

Use "Favorites" to bookmark and quickly retrieve any document.
Use "Tags" to organize Tarius documents by project or topic.

When You Need to
Share Information with Colleagues

Share documents with ease with your colleagues across the organization.

Tarius' web-based interface means every document has a web address, making it easy to bookmark, locate, hyperlink, and share key documents.

When You Need
Company-Specific Research

Get customized regulatory research across the global landscape. Tarius offers project-based research tailored to your specific needs.

Our network of regulatory experts around the world is available to answer specific regulatory questions and/or perform regulatory intelligence and strategy-related activities to help your company make better, more informed decisions.

Tarius A/S · Klerkegade 19 · 1308 Copenhagen · Denmark · www.tarius.com · sales@tarius.com · +45 7211 2124

TARIUS