



Compliance Navigator

for Medical Devices



Stay informed. Stay compliant.

Standards, regulatory and guidance information is often distributed across various sources, and relying on existing hard copies can be limiting. Tailored to the specific needs of medical device manufacturers, Compliance Navigator is a unique, user-focused service that transforms the way you manage the compliance needs of new and existing medical device products in your portfolio and development pipeline.

Compliance Navigator shrinks the haystack of information for your device – a simple search unearths the most relevant and current information you need.

Don't search for documents; search for devices.

All you need to do is let Compliance Navigator know what kind of device you're designing or manufacturing and it will bring the documents to you – saving you valuable time and effort in obtaining and maintaining conformity. It gives you the confidence that the documents you see are related to your needs and are only a click away.

No need to print or save large PDF files.

View documents in full-text and take advantage of links between documents to relevant sections or companion standards within Compliance Navigator and external sources. Create and save documents to a product profile and share it with others within your organization so that everyone is using and accessing the same information. You'll also be able to add and remove content when needed – ensuring your product's documentation evolves along with your product design and manufacturing needs.

Gain a long-term view of how the regulatory profile of your products will evolve over time.

Compliance Navigator will inform you when a document you're using for your device has entered the revision process, what stage of revision it is currently in and what type of revision it is going through. You can reduce your time spent finding and tracking potential and actual developments – leaving you more time to assess the risk to your business and plan accordingly.

...making excellence a habit.™

Compliance Navigator delivers the right information, at the right time, to help you make the right decision. It's that easy.

- **Discover** applicable compliance requirements for specific devices with our innovative, intuitive guided search
- **Manage** the regulatory profile of your whole product portfolio at product level
- **Assess** the impact of changes on specific devices with less investment of time and effort
- **Gain** a long-term view of forthcoming changes that may affect the compliance of individual products
- **Share** compliance information across your whole team, so that you're confident that the right information is being used at the right time.

How do you know that you're always on top of all the latest compliance information?

If you're like most medical device developers and manufacturers, the search for relevant compliance information can be laborious and costly. Regardless of how you find and manage critical information – whether through search engines, online catalogues, PDFs, spread sheets, shared drives, hard copies of standards or other bespoke services – discovering and assessing this information can be incredibly time consuming.

The content is trusted and authoritative.

Developed by BSI, the service benefits from our wealth of experience, expertise and authority in medical devices. Compliance Navigator has been created especially for the medical devices industry with your specific challenges in mind – saving you time, money and effort in meeting your compliance obligations.

Guided by GMDN. BSI Compliance Navigator utilizes the Global Medical Device Nomenclature (GMDN) terms database to enable intelligent guided searches by device type, application and category, in accordance with GMDN's internationally recognized generic descriptors. By partnering with the GMDN Agency, a non-profit organization whose database has been adopted by over 50 national medical device regulators, Compliance Navigator uses state-of-the-art semantic enrichment and linked data to help deliver the highest level of accuracy in search results in seconds, to locate the standards and regulatory information which have a direct and specific impact on the compliance of your medical device portfolio. For further information on GMDN please refer to gmdnagency.com.

Compliance Navigator makes manual redlining a task of the past.

Highlight changes between versions at the click of a button, so you can quickly assess the impacts for your business. Expert commentary – exclusive to BSI – provides context and guidance – helping you assess, review, plan and implement changes more effectively and with plenty of notice to remain compliant.

Why not see the difference Compliance Navigator can make to workflow efficiency in your organization? For further information, to arrange a demonstration or to register for your free trial, please contact us today.

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