INDUSTRY BULLETIN

# FDA Establishment Registration Requirements for Contract Manufacturers

## What Medical Device Customers Need to Know

In the United States, the Food & Drug Administration (FDA) requires any company that manufactures a finished medical device intended for commercial distribution in the U.S. to register its manufacturing facility and to list those devices. This includes contract manufacturers manufacturing finished devices on behalf of the legal manufacturer.

This bulletin explains the regulatory requirements and the position and responsibilities of Saint-Gobain as a contract manufacturer serving the medical device industry.

## Compliance Position of Saint-Gobain

The FDA defines a contract manufacturer as an establishment that manufactures a finished device to another establishment's (the device owner's) specifications. Under FDA regulation 21 CFR Part 807, such manufacturers must register their facilities and list the devices they produce for U.S. distribution.

FDA regulation **21 CFR §820.3(l)** defines a **finished device** as one that is capable of functioning as intended, even if not yet packaged, labeled, or sterilized. Accessories that are intended to support, supplement, or augment the performance of a parent device are also considered finished devices when they are supplied in their finished state.

Based on these definitions, Saint-Gobain acts as as a contract manufacturer and in accordance with FDA requirements, registers facilities that manufacture finished devices, including accessories, for commercial distribution in the U.S., when those products are not further transformed by our customers.

## When Registration Is Not Required

FDA registration and listing apply only when finished medical devices enter U.S. commercial distribution. Products made exclusively for non-U.S. markets (e.g., Europe) do not trigger US FDA requirements. Device manufacturers must instead follow the regulations of the country where the device will be sold.

Registration is also not required when Saint-Gobain supplies components that are further transformed by the device manufacturer through qualifying manufacturing steps – such as cutting, assembly, or welding – that alter the product into a new finished form. Packaging, labeling, or sterilization alone do not qualify as transformation steps.

If a product reaches the end user without further transformation and can function as intended, it is considered a finished device, and FDA registration requirements apply.

## Why the Distribution Path Matters

Whether a Saint-Gobain product is categorized as a component, or a finished device depends on how it is sold and who receives it.

For example, a filter installed by a device manufacturer inside their equipment is considered a component. However, if that same filter is later sold directly to a hospital as a replacement part, it becomes an accessory because it reaches the end user ready to function. As a result, FDA requirements for finished devices apply.

Categorization of Saint-Gobain products depends on intended use, distribution pathway, and country of sale. For this reason, we work closely with our customers to align on requirements and support compliant market entry.

## Clarity on Device Specification Ownership

Saint-Gobain supplies high-quality materials and components but is not the legal manufacturer of finished medical devices. Our product specifications are general product specifications and are not intended to serve as device-specific design inputs under 21 CFR §820.30 to support a specific medical device intended use.

When our components are incorporated into a medical device – or when we manufacture to customer-provided specifications – the legal device manufacturer is responsible for confirming that the component is suitable for its intended use and for defining any additional specifications required to ensure the safety, effectiveness, and compliance of their device.

In summary, our customers retain ownership of the specifications for their finished medical devices, while Saint-Gobain supports this responsibility by providing product data and manufacturing process technical support.

## What Registration Means in Practice

Saint-Gobain FDA Registration includes:

- Annual electronic establishment registration for all applicable Saint-Gobain manufacturing sites
- Listing of finished devices and accessories manufactured for distribution in the U.S.
- Visibility of our manufacturing sites for potential FDA inspections
- Maintenance of quality systems aligned with 21 CFR Part 820

At its core, FDA registration ensures that Saint-Gobain operates within a compliant quality system and is fully prepared to demonstrate adherence to regulatory requirements. Registration as a contract manufacturer is the sole responsibility of Saint-Gobain.

Customers play a supporting role by providing applicable information necessary for complete registration, including:

- FDA Product Code(s)
- Customer’s Device Proprietary Name(s)
- Customer’s 510(k) or Premarket Authorization Number(s), if applicable
- Customer’s Establishment Registration Number
- Customer’s Owner/Operator Number

## A Standard Across the Industry

FDA registration for contract manufacturers is a long-standing legal requirement. Since updates to 21 CFR Part 807 in 2012, all contract manufacturers of finished devices for the U.S. market must register and list those devices.

Saint-Gobain monitors evolving regulatory expectations to help ensure our practices remain aligned with current requirements. We are committed to maintaining clear compliance pathways, strong quality systems, and open communication with regulatory authorities and our customers.

## Closing

Saint-Gobain remains committed to regulatory compliance and quality excellence across all facilities. As a contract manufacturer of finished devices, we maintain FDA-registered sites in the U.S., EU, and Asia. As market conditions or regulatory guidance evolve, we will continue to work closely with our customers to ensure ongoing compliance and shared success.


## Author

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Morgan Duke is the Global Quality and Regulatory Director for the Medical Business Unit of Saint-Gobain Performance Plastics, responsible for overseeing the quality systems and regulatory compliance of medical products. With 15 years of experience in quality systems and medical device regulatory affairs, Morgan brings deep expertise to ensure robust compliance and operational excellence.


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