Press Release/

Expanite receives a Master File for Devices (MAF).

Expanite receives a Master File for Devices (MAF) acknowledgement letter from the FDA for its patented process for surface hardening of stainless steel in medical device applications

Expanite announces it has submitted a Master File for Devices (MAF) to the United States Food & Drug Administration (FDA) and has now been issued the submission number MAF3078.

Expanite has successfully submitted a Master File for Devices (MAF) to the Center for Devices and Radiological Health (CDRH) at the FDA for SuperExpanite®, their patented process for surface hardening of stainless steel and received an Acknowledgement letter from FDA confirming submission filing. The MAF covers necessary information such as technology, production processes and facility information, as well as test data and more. The SuperExpanite Master File has been issued a submission document control number MAF3078.

"We are very pleased to have achieved this significant milestone. The FDA registration makes it easier for our U.S. customers to obtain approval for new medical products that use Expanite surface hardening. Expanite is now able to provide a signed and named Authorization letter to our customers on their request, for their product registrations at FDA. This is the first of many MAFs to come," says Expanite CEO, Thomas Abel Sandholdt.

Benefits of MAF implementation

The advantages of the MAF being submitted to FDA for the manufacturers who utilize Expanite surface hardening technology and register their products at FDA are many, e.g.:

Expanite, individually, invested time to search and understand the FDA requirements for MAF submission.

- Documentation compiled, as required, and submission confirmed by FDA;
- Surface hardening technology documentation available for FDA's review as of now;
- Eliminates communication time and effort between the manufacturer and Expanite on MAF build and requirements;
- Expanite is responsible for maintaining MAF up to date, as appropriate

For the manufacturer's medical devices registration purposes, the SuperExpanite Master File for Devices is now available for reference and review at FDA. Expanite shall provide MAF Authorization letter on customer requests to make Expanite technical documentation available for FDA's review in context of their product registration.

Please contact Thomas Abel Sandholdt to hear more about the FDA Master File for Devices, SuperExpanite MAF content and request a signed and named Authorization letter for your product registrations.

About Expanite

Since 2010, Expanite has provided proven and reliable heat treatment and surface hardening solutions for stainless steel, titanium, nickel-based and other speciality alloys. Our solutions improve wear, galling and corrosion resistance, thereby extending the lifetime of critical components, minimising the need for virgin materials. The company has its head office in Hillerød near Copenhagen and service centers and licensees in Germany, USA, Korea, and China. The patented business model allows for license agreements whereby customers may implement the technology in their production lines. www.expanite.com.