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Webinar on

Critical Planning for Exporting Devices to the EU

Learning Objectives

- *EU legal requirements for exporting devices*
- *FDA legal requirements for exporting devices*
- *CE certification renewal*
- *Redelivery of cargo*

What do you do when your exported devices do not have a valid CE Certification?

PRESENTED BY:

Casper (Cap) Uldriks, through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. He conducted domestic and foreign inspections. He specialized in the FDA's food and medical device programs as a field investigator, served as a senior manager in the Office of Compliance at the Center for Devices and Radiological Health (CDRH) and as the Associate Center Director for Regulatory Guidance and Government Operations at CDRH.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Exporting devices to the EU has new EU legal requirements. A device must have a valid CE mark. You must renew your CE mark certification every three years. If you do not, your products cannot be marketed legally in the EU. If your product is not marketed in the U.S. Many U.S. devices are legally marketed in the EU, not the U.S., renewing your CE certification takes planning, a lot of planning. It is not automatically renewed. Now firms face an expensive, time consuming and uncertain outcome of renewing their CE mark. The recertification process is not the same for all products. The CE certification review will depend on the MDR classification associated with safety issues and performance specifications, not the U.S. classification. Even worse, devices using outdated technology may face a costly surprise when their device is deemed “out of date” and can no longer be marketed.

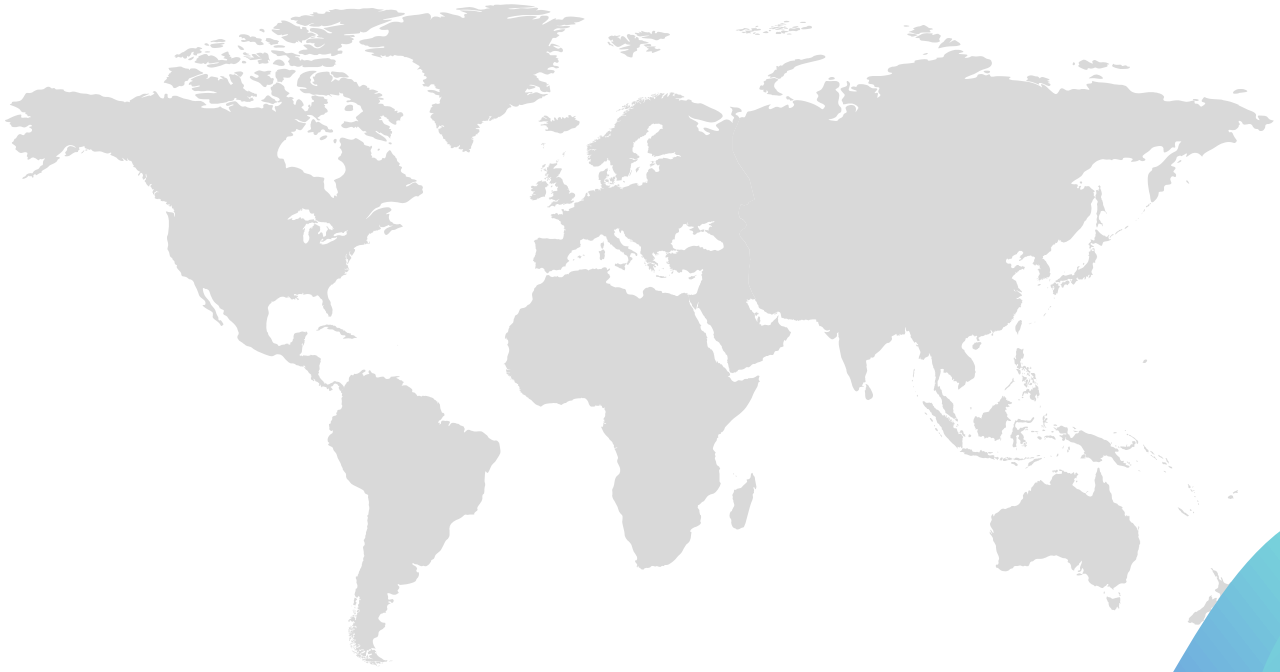
What do you do when your exported devices do not have a valid CE Certification?

Have you prepared for this MDR requirement? If you are not prepared for this change in the law, your options for selling your device will not include the EU nor the U.S.

The European Union (EU) has implemented a new law, the Medical Device Regulation (MDR), that imposes new requirements on U.S.devices exported to the EU. If your device does not have a valid CE mark certification, it cannot be legally marketed in the EU. The device(s) are in conflict with EU countries and, therefore, may consequently fail to meet the U.S. FDA's export legal requirements you used to export the product in the first place. What happens to your shipment?

Who Should Attend ?

Exporters EU Authorized Agent
Regulatory Affairs Director
Export Logistics Manager
Quality Assurance Manager
Manufacturing Operations Managers
Complaint Department Manager



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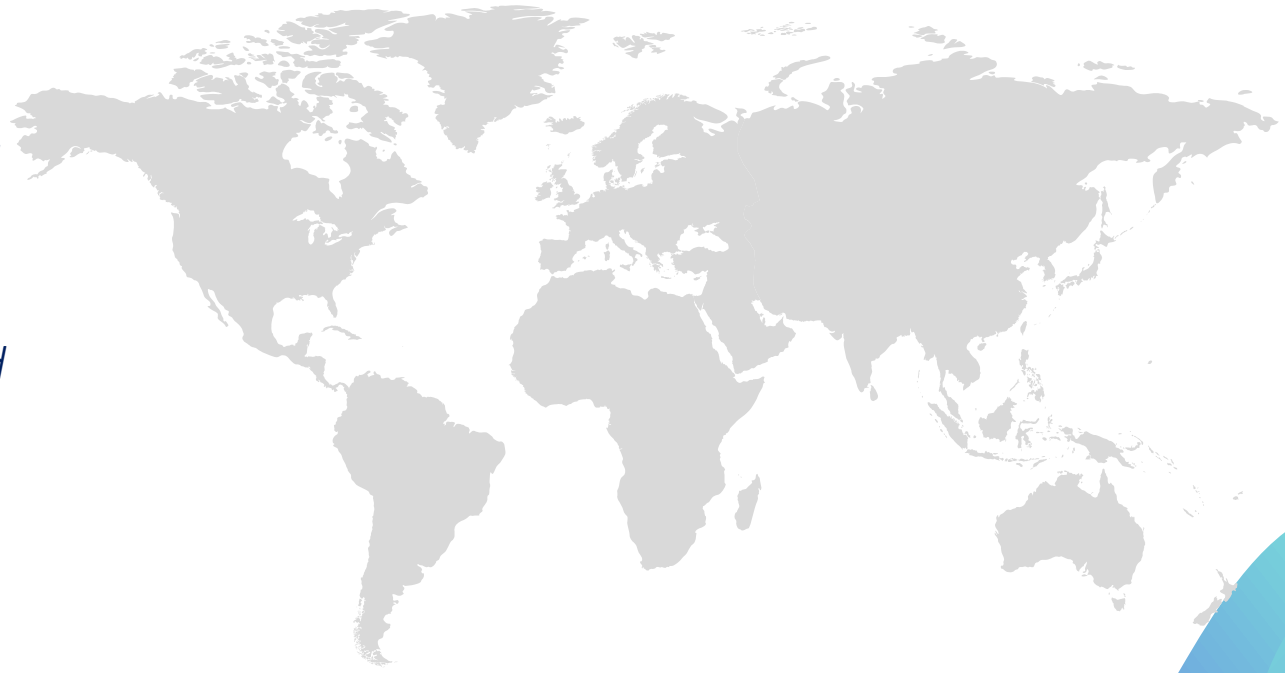
Why Should Attend ?

The EU's Medical Device Regulation (MDR) requires, among other things, that marketed devices have a valid CE mark certification. CE marks have a three-year expiration date. Without a valid CE mark, your device cannot enter the EU market. The process and criteria for obtaining a new CE mark impose unprecedented demands that can stop your export business in its tracks. Resolving the problem may be too expensive relative to net profit and of no value to your demographic. You lose out to your competition due to your failure to prepare and compete with the new MDR requirement. FDA export law does not give you the option of returning the product to the U.S. What is your next step to avoid losing your EU customers?



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