CE manufacturer

GIMA IS MANUFACTURER OF OVER 1,500 PRODUCTS
Conform to Europe's Medical Devices Directives

Among Europe's three medical device directives:
- Active Implantable Medical Device Directive 90/385/EEC.
- Medical Device Directive (MDD) 93/42/EEC.
- In Vitro Diagnostic Directive 98/79/EC.

The definition of what constitutes a manufacturer is identical: "Natural or legal person with responsibility for the design, manufacture, packaging and labeling (sic) of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party."
The OBL process adopted by Gima, works with its partners to assist in the OBL procedure to understand the requirements to secure CE marking.
Specific areas covered:
• Responsibilities of the OBL and OEM.
• Role of the Notified Body.
• Situations where a lighter OBL approach apply.

The OBL is the “manufacturer” of the product when a product is labeled with the OBL name and contact information. As a result, the OBL assumes the corresponding “manufacturer” responsibilities according to the applicable European Directive.

The pivotal provision that qualifies a medical device manufacturer, as such, is the characteristic of placing the medical device on the market "under his own name."
The manufacturer clearly is responsible for the medical device manufacturing operations, though the functions described can be variously delegated or subcontracted. And many manufacturers variously have subcontracted the design, manufacture, packaging and labeling operations of their medical devices.

Following are some groupings that have been acknowledged as individual models of medical device manufacturers:
• Conventional medical device manufacturers perform all functions of medical device manufacturing on their premises/facilities.
• Some manufacturers outsource portions of their manufacturing.
• Virtual manufacturers outsource all medical device operations.
• Some manufacturers assemble systems and procedure packs.
• Many more manufacturers contract with manufacturers that already possess CE marking so they can brand the devices as their own.

Discussion is not required to explain the conventional medical device manufacturer that, in its own facilities, on its own premises, physically makes the product and performs all the functions: design, manufacture, packaging and labeling.