WHO ARE ALL THESE CE PEOPLE?

FROM THE TOP DOWN IN PLAIN ENGLISH:

THE EUROPEAN COMMISSION

The government agency responsible for writing all product legislation, including medical devices, which are published as Directives. Medical Device Directive 93/42/EC, when published in the 'Official Journal', was adopted into National law by each EU State. When adopted each EU State gives it their own name and number, which often leads to confusion. This Directive has been reviewed and amended, the changes go into effect on March 10, 2010.

THE COMPETENT AUTHORITIES

Equivalent of the US FDA, except every EU State has one. Germany has five! They supervise and often provide 'interpretations' to Notified Bodies.

NOTIFIED BODIES

European Certification Agencies. They are for profit! In order to become a Notified Body these agencies must apply to the Competent Authority in the country where they originate to become accredited in accordance with the Medical Device Directive. They have to prove that they have expertise in certain medical device areas before they become accredited in accordance with a certain 'scope' of accreditation. All EU countries accept certifications from all EU Notified Bodies. They sometimes try to tell you that it is better for you to hire a specific country Notified Body for specific customers, etc. Frankly that is plain nonsense.

Notified Bodies close agreements with manufacturers to audit their quality management systems and technical files for the purpose of CE-marking of devices in risk class 1+sterilization or measuring function; IIa, IIb, and III. They may not get involved with Risk Class 1 devices which may be CE-marked in accordance with the self-certification route outlined in the directive.

Notified Bodies are supervised and reviewed by the Competent Authorities. There have been cases of cancellation of Notified Bodies due to poor performance

Notified Bodies may not perform consulting work and cannot be authorized representatives, it is considered a conflict of interest.

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Manufacturer and its Authorized Representative

The Directive is very clear about its definition of the manufacturer, in short it is the party that places its name on the device label. There may be only 1 name and it must be identified by the 'manufacturers' symbol.
If the manufacturer is domiciled outside the EU it must hire an Authorized Representative domiciled in the EU (Example: QNET B.V. in The Netherlands) for regulatory affairs! Not Sales and Marketing. This name must appear on all labels and inserts identified by the 'Authorized Representative' Symbol, they must keep a copy of the confidential technical files. The Notified Body usually looks for an agreement that clearly outlines this relationship, The Competent Authorities contact the AR in case of problems. It is a unique way of bringing a non-EU manufacturer into their legal jurisdiction.
The US FDA has a similar system for anyone manufacturing outside the USA, it is called US FDA Agent. QNET provides those services as well. There are differences between the EU and US system.
There are quite a few OEM situations that try to place several names on a device label with a statement such as:

> **Manufactured for (Company Name) by (Second Company Name), this is not acceptable under the medical device directive because it clearly confuses who the manufacturer is and who carries the responsibility/liability.**

A CE-MARK IS NOT TRANSFERABLE!

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