

## The Contractual Obligations of Outsourcing Companies and Vendors

Recently, mdi Europa has received many questions with regards to private labelling issues. Thus, in this article we will consider how the responsibilities and roles should be reflected in the contract between the outsourcing manufacturer and the third party or contract manufacturer. Apart from the Declaration of Conformity, there is no document that has such an essential position in assigning responsibility for product quality, regulatory compliance and product liability as the contract.

One of the first problems that we are confronted with is the lack of consistent definitions for the outsourcing party, the contract manufacturer and the “own-branders” that manufacture their own goods.

### MDD Definition

The only legal basis, in the strict sense, for the definition of a manufacturer is given in the Medical Devices Directive under article 1

*“Manufacturer means the natural or legal person with responsibility for the design, manufacture, packaging and labelling 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 or on his behalf by a third party”*

This definition easily allows for the conclusion that a great deal of outsourcing, most or even all of design and production is allowed before the distinction between manufacturer and marketer becomes blurred. The question then is who resumes responsibility for placing the product on the market?

Even if the production of the product is carried out by a third person the manufacturer still takes full responsibility for the product once it is on the market. According to the only government source that has issued a brochure covering this important and complicated subject, the “own brander” is the person who places the product on the market under his own name or trademark and is therefore the manufacturer for the purpose of the regulations. The manufacturer must ensure the adequacy of and the compliance with acceptable standards of the quality system. The manufacturer must issue his own Declaration of Conformity in order to assume his responsibility. If the contract manufacturer maintains his own name on the label, then it becomes important to show who is the manufacturer, as this entity is solely responsible for placing the product on the market and its implications. Similar, though somewhat different, considerations apply to the distributor. A decent contract between the parties is therefore vitally important.

**The following items should be covered by the contract:**

- Name(s) and addresses of the contracting parties
- Name(s) and descriptions of the products to be produced by the third party manufacturer
- Trade name(s) of the products to be produced and who shall assume responsibility for placing those products on the EU market
- The exact descriptions with their respective responsible parties that the outsourcing manufacturer will delegate.
- Access to and interaction between parties concerning drawings, production methods, specifications, etc.
- A definition of the right of the outsourcing party to inspect or audit the producer
- Which rules and regulations shall govern the production of the outsourced items (local, international)
- Which Notified Bodies and minimum quality standards shall govern this outsourcing relationship
- The extent to which the outsourcing party has a say over the supplier management or change of particular materials, designs or specifications of parts materials by the third party producer.
- The actions required in case of non-compliance with local regulations, or if either of the two parties becomes subject to government enforcement measures
- The same applies to other production disruptions
- Who is the owner of the product and until when?
- Who is responsible for and has access to the investigative results of actual or alleged product defect
- Who owns the intellectual property
- Any remedial actions and/or sanctions
- Liability

These points are all critical and are sometimes fairly technical in nature, some contracting parties elect to draft a document separate from but always linked to the usual commercial agreement. Some of the points mentioned must transcend the lifetime of the agreement because when a relationship between an outsourcing manufacturer and his third party producer comes to an end, the products are still being sold.

The above matter is complicated but is very important to the safety, quality and regulatory compliance of medical devices.