CE MARKING FOR OWN BRAND LABELLED MEDICAL DEVICES

Jan Petrik

The Regulatory World

Who is the Manufacturer ?

Who (the natural or legal person) places the product on the market under his **own name** or **trademark** is the manufacturer.

Although he may not be the person who designed, manufactured, packaged or labelled the product (e.g. on an contractually basis) but nevertheless

⇒ **the regulatory responsibility rests with him alone.**

He must ensure that all requirements of the directive are fulfilled, also at the site of his sub-contractors.

OEM vs OBL

ORIGINAL EQUIPMENT MANUFACTURER

OEM designs and manufactures medical devices which are already placed on the market under **his name**

OWN BRAND LABELLING manufacturer

Own Brand Labeller is the company/person who places on the market under **his own name** or trademark a device **already CE marked** by an OEM and is therefore the manufacturer (as defined) for the purpose of the regulations

Who is NOT Considered as OBL

- **a legal manufacturer may not actually carry out any design or manufacturing activities themselves but have them performed by third parties on their behalf and they are placing MD(s) on the market for the first time – virtual manufacturer.**
- **a legal manufacturer is purchasing finished devices to label with their own name but which have NOT already been CE marked by the original manufacturer.** *The Notified Body would need to assess the full technical documentation for the device to verify compliance of the device.*
- **a distributor whose name appears on the packaging, labels or instructions for use is NOT considered to be an Own Brand Labeller if it is clear that the product is sold under the actual manufacturer's own name.**

CE Marking of OBL

- it is responsibility of the OBL to meet all regulatory requirements. The device must be covered by the **OBL's conformity assessment** certificate and be approved by the **OBL's notified body**
- the conformity assessment relating to the device itself will consist of verifying that the **existing CE marking** conformity approval held by the OEM (the "third party" providing the device to the OBL) is valid and current, and that the device in question is the **same device.** The assessment therefore needs to cover **sufficient documentation** to demonstrate this

Requirements to OBL Documentation

- **Declaration of Conformity**
- **Description of devices (**identity of OEM/OBL MDs; classification; index of OEM TF**)**
- **Copies of the OEM's certificates (CE, QMS, etc.)**
- **OBL QAS documentation (**vigilance & post-market surveillance**)**
- **Labeling procedure;** OEM labels vs OBL draft labels
- **OEM/OBL devices' IFUs**
- **Solutions adopted to meet the essential requirements**
- **Results of the risk analysis**
- **Regulatory contract between OEM and OBL**

OEM - OBL Regulatory Contract

OEM must transfer enough information to OBL so that he can become a manufacturer and vice versa OBL must take sure that he become possessed of sufficient information/documentation in order to take the responsibility as manufacturer.

A contract must meet the requirements in the directives and protect the OEM for loss of valuable know-how about his products:

- scope: companies involved, products (traceability), period of contract validity
- agreements upon changes in production/certification of OEM (regulations governing relevant procedures: testing)
- vigilance & recalls (+complaint handling & information of the partners)
- OBL access to technical documentation (rules for maintaining the documents and records/valid documents - responsibility for these, also after the business relation has finished)
- NB & CA access to OEM's premises & technical/production/registration documentation – inspections/audits

Post-Production Obligations

The conformity assessment needs to cover the mandatory QS requirements to ensure that the OBL can meet the Directive(s) obligations as the legal manufacturer, including documents for:

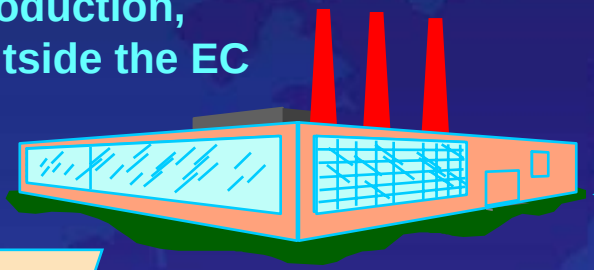
- Procedures for labelling of the device and display of the CE marking
- Procedure to prepare and review a Declaration of Conformity
- Process to identify what is a significant change and what should be notified to the NB
- Procedures for registration with Competent Authorities
- Process for selection and control of the OEM, demonstrating responsibility for design, manufacture and labelling of the product

In case the classification requires conformity assessment by a full quality assurance route the OBL will need to demonstrate design control procedures, even though in effect he has sub-contracted the design activities to the OEM.

Import & Sale

Design and production, outside the EC

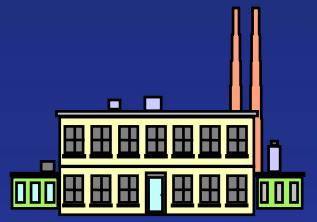
" P "



Certificate Annex II or other

contract

Sales under name ”P” within the EC



" I "

Contract: legal requirements, documents of the QA-System of the products/technical and production.

or

representative of ”P"

- Keeps the documentation (actual)
- Informs of the authorities

Labeling

Manufacturer ”P”, address
Product: 55553434341
Charge cc

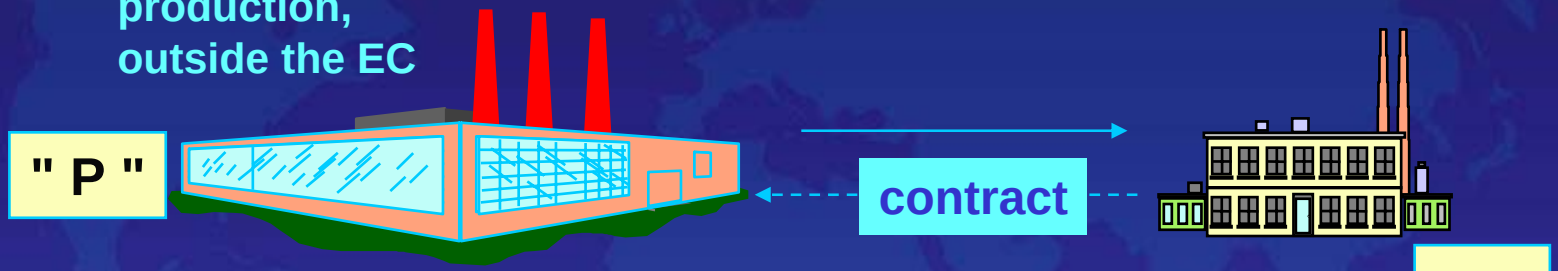
CE_{1023}

Importer or representative in the EC
e.g. " I" or ”R“, address

Import & Sale

Sales under name ” I ” within the EC **!**

Design and production, outside the EC



Contract: legal requirements, documents of the QA-System of the products / technical and production.

Certificate Annex II or other

Labeling

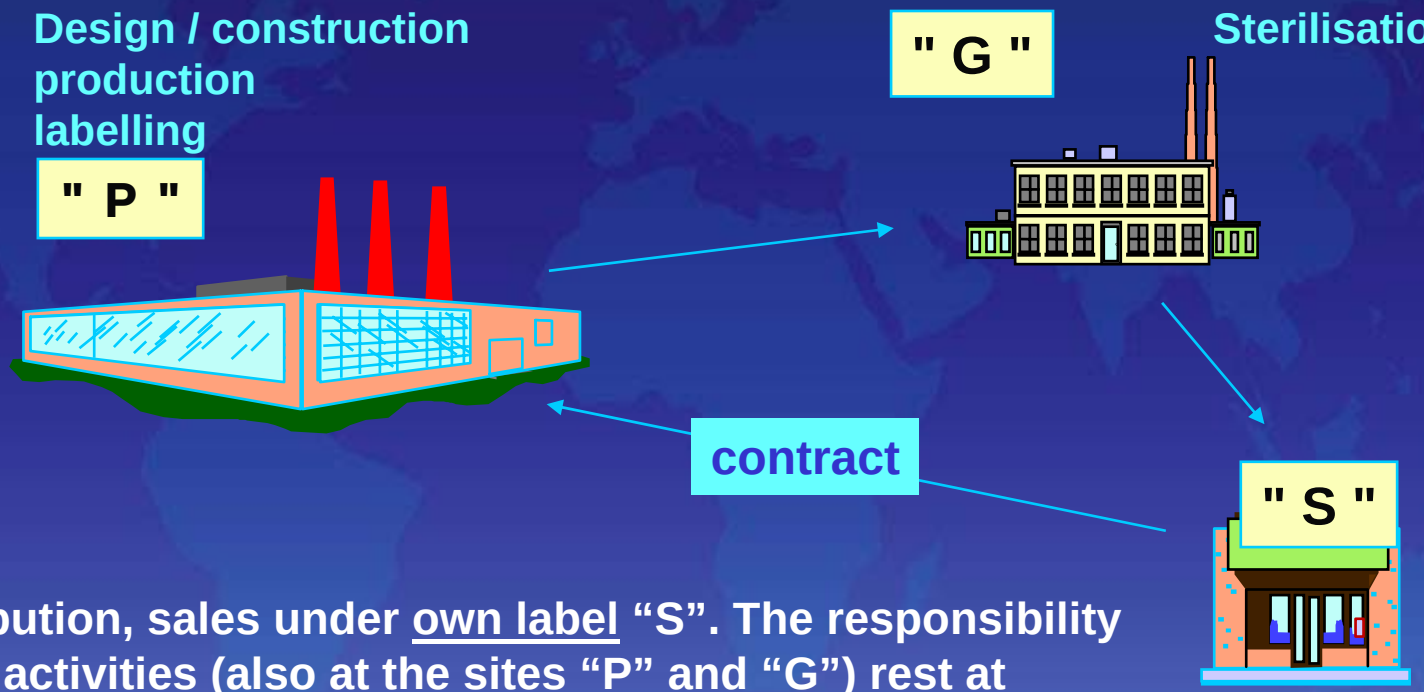
Manufacturer ”I", address

Product: 55553434341
Charge cc
CE_{1023}

- Maintains a QA-System
- Informs of the authorities
- Keeps the documentation (actual)

“I” is the (virtual) manufacturer

The Economic World is More Complex



Distribution, sales under <u>own label</u> "S". The responsibility for all activities (also at the sites "P" and "G") rest at company "S" alone !

"S" has to present to the auditor all documents, proofs and records necessary to verify that the legal and normative requirements are fulfilled. If necessary the auditor has to perform audits at all sites !

Own Label, Import or Domestic

Case 1: All documents necessary are at the site of "S". These are maintained on an contractual basis.

Not realistic. Especially for the activities: design, production, testing. The know-how of the company "P" would be transferred to "S".

Case 2: Company "S" refers in its QA-documentation to the documents and procedures at the site of company "P". Company "P" holds its product and system specific documents alone. The responsibilities for the documents and for the common procedures (QA-system) are laid down in a contract. By supervisions (audits) "S" proves if "P" maintains the contractual requirements.

No <u>complete</u> evidence can be achieved that "P" holds all legal demands / requirements.

Own Label, Import or Domestic

Case 3: "S" holds the technical documents (Product Master File, Risk Analysis). The responsibilities for the documents and the procedures at site "P" are ruled in a contract. Company "P" is certified acc. to EN ISO 13485 by a notified body.

Approval acc. MDD - annexes for "S" can be possible without an audit at the site "P". This depends from the completeness and contents of the documents. Certificate acc. to ISO 9001 is not sufficient.

Case 4: "S" holds parts the technical documents (Product Master File, Risk Analysis is for its own activities). The relationship and the main common procedures with "P" are contractual. "P" holds an approval by a notified body for the identical products under its own name acc. to a suitable annex of the MDD.

Approval acc. MDD - annexes for "S" will be possible without an audit at the site "P". This depends from the completeness and contents of the documents. The identity of the products under consideration must be demonstrated.

Deficiencies From Our Experience

- list of applicable documents, e.g. standards, directives, IfUs, labels – usually not updated & incomplete
- external approvements for the product itself are missing or they are not applicable to it (EN ISO 60601, EN 550, 552, 554 ...)
- risk analysis is not complete, the fulfillment of the essential requirements is not completely demonstrated. The residual risks are not evaluated (elaborated just in formal manner)
- there are evidences missing, that the products hold the stated capacities, specifications (if necessary: clinical studies)

Thank you for your attention

Jan Petrik, PhD.
Institute for Testing and Certification, Inc. Zlín
Branch Office ITC Slovakia,
Mlynske Nivy 54
SK-821 05 Bratislava
SLOVAK REPUBLIC

jpetrik@itczlin.cz
www.itczlin.cz
phone +421 2 5342 1046
fax +421 2 5342 1032