Frequently asked questions about the role of the European Authorized Representative for Non-EU manufacturers of medical devices

1) **Why do we need to select an Authorized Representative, if we are located outside Europe?**

- Because it is a requirement clearly stated in Medical Device Directive 93/42/EEC and In-Vitro Diagnostic Device Directive 98/79/EC.

2) What are our options?

- You may select an agent, distributor, or independent Authorized Representative domiciled in the EU.

3) How do we choose between an agent, distributor and an independent Authorized representative?

Consider the following:

- Do you want your distributor to focus on sales and marketing or on regulatory affairs?
- Will your distributor in country A object if the name and address of your distributor in country B appears on all devices, inserts and packaging? Be aware that you may appoint only one authorized representative per device for the entire EU.
- Will it lead to distribution/warranty confusion if the name and address of distributor A appears on all devices in all EU states?
- If you change distributors will it be costly to change all device labels, inserts and packaging?
- If you cancel a distributor will they release national registrations (Italy, Spain and France) voluntarily? Or will this be subject to (financial) negotiations?
- Do you feel comfortable having your distributor represent you in front of the Competent Authorities (equivalent of USA-FDA)?
- The authorized representative role must be clearly defined in an agreement in accordance with the EU MEDDEV document. It is important to know how to define the authorized representative as a non-crucial, non-critical supplier of services.
- If the Competent Authorities question an accident or a non-compliance that occurred in the distribution system will your distributor defend his company or yours?
- If your distributor is unable to answer the Competent Authority's questions does anyone in your company have the knowledge to do so correctly?
- Are you comfortable placing a technical file containing design information with your distributor?
- Does your distributor stay up-to-date on EU regulatory changes and will they provide you with timely warnings when changes affect your devices?

4) Do independent Authorized Representatives sell medical devices in Europe?

- Commonly they do not sell devices; they do not compete with your distributors and/or agents.

5) How do we select an Authorized Representative?

- Based on references, giving you a clear idea of the service level and experience provided. The agreement must meet the: A) Medical Device Directive 93/42/EEC or In-Vitro Diagnostic Device Directive 98/79/EC; B) MEDDEV 2.5/10 Guideline; 2010 NBOG's Best Practice Guide and C) Decision No. 768/2008/EC, which clearly defines the role of the Authorized Representative.
- Stability of a fixed annual fee structure and issuance of an annual review are very important.

6) **How should we determine the Authorized Representative's essential duties?**

If you determine that you need an Authorized Representative defined as a non-critical/non-crucial supplier of services that do not influence the safety and performance of your devices you need to tailor the essential duties accordingly in the authorized agreement.

If you determine that you need an Authorized Representative defined as a critical/crucial supplier of services that do influence the safety and performance of your devices you need to clearly outline this in the essential duties outlined in the Authorized Representative agreement.

Important Note: It is the responsibility of the manufacturer to determine which are critical items or processes and how their purchase is controlled. This depends on the manufacturer's risk management activity, etc.

7) What does the Authorized Representative expect from us, the manufacturer?

- Device compliance with the Medical Device Directive 93/42/EEC or In-Vitro Diagnostic Device Directive 98/79/EC requirements for all risk devices
- Placing of the entire device technical file in its trust, as required
- Immediate notification of device incidents
- Full cooperation with requests from the Competent Authorities
- Product liability insurance coverage that includes the EU and the authorized representative.
- Indemnification of device liability

8) How do we keep the file up-to-date?

- The authorized representative should, at a minimum, provide you with an annual review of the technical documentation held in the EU and remind you to up-date.

9) Is all the information/documentation that we place with the Authorized Representative confidential?

- Confidentiality should be covered in the agreement between your company and the selected authorized representative in accordance with the Directives which states that all parties, authorities and Notified Bodies included, are bound to observe confidentiality with regard to all information.

10) Why do Authorized Representative agreements include a penalty clause in case of a contractual violation by the manufacturer?

- The Authorized Representative is subject to EU Law; however the manufacturer resides outside the EU Legal Jurisdiction and may decide not to cooperate with the EU Authorities. To prevent the Authorized Representative's exposure of being on the receiving end of a manufacturer's liabilities, the penalty clauses provide recourse.

11) If we cancel our Authorized Representative agreement do all duties stop immediately?

- No, the Authorized Representative's name remains on devices already sold and still in use, resulting in the continuation of some obligations even after cancellation of the agreement.

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