ASPHALION MedTech

EU Authorised Representative, UK Responsible Person & US Agent

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Authorised Representative

When a **manufacturer that is not established in a Member State** wants to place a device on the European Union market, an **authorised representative is required**.

The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The mandate shall require the authorised representative to perform at least the following tasks:

- Verify that the EU declaration of conformity and technical documentation have been drawn up.
- Keep a copy of the technical documentation and the EU declaration of conformity available to competent authorities for at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market (15 years in the case of implantable devices).
- Comply with the registration obligations, and verify that the manufacturer has complied with the registration obligations including UDI system.
- Provide the competent authority with all the information and documentation necessary to demonstrate a device's conformity, in an official Union language, upon request.
- Forward any request for samples or access to a device to the manufacturer, and ensure that the competent authority receives the samples or is granted access to the device.
- Cooperate with the competent authorities on any preventive or corrective actions taken to eliminate or mitigate risks posed by devices.
- Immediately inform the manufacturer of complaints and reports from healthcare professionals, patients, and users regarding suspected incidents related to a device for which they have been designated.

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Authorised Representative

However, **the mandate shall not delegate some of the manufacturer's obligations** such as:

- Device design and manufacture in accordance with the MDR.
- Risk management system.
- Clinical evaluation.
- Preparation and maintenance of technical documentation.
- Preparation of EU declaration of conformity.
- Production conformity with the MDR.
- Establishment of the Quality Management System.
- Post-Market Surveillance system.
- Information Supplied with the Device.
- Device withdrawal or Recall.

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UK Responsible Person

Manufacturers located outside the UK must designate a UK Responsible Person to market a device in Great Britain (England, Wales, and Scotland).

Duties of the UK Responsible Person include:

- Registering the devices with the MHRA
- Maintain a copy of the technical documentation, declaration of conformity, and any relevant certificates, available for MHRA inspection
- Verify that the declaration of conformity and technical documentation have been prepared
- Provide the MHRA with necessary information and documentation to verify a device's conformity.
- Collaborate with the MHRA on preventive or corrective measures to eliminate or mitigate device-related risks
- Comply with MHRA's requests for samples or access, or forward MHRA requests for such to the manufacturer and inform the MHRA of the manufacturer's intent to comply
- Promptly inform the manufacturer of complaints and reports from healthcare professionals, patients, and users concerning suspected incidents with the device
- The UK Responsible Person's name and address must appear on the product labeling, outer packaging, or usage instructions when the UKCA marking is present

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US Agent

A **United States agent (U.S. Agent) must be designated** for any foreign establishment involved in the manufacturing, preparation, propagation, compounding, or processing of a device imported into the United States.

The **responsibilities** of a U.S. Agent include:

1. **Assisting the FDA in communicating with the foreign establishment.**

2. **Maintaining a business location in the U.S. Being available to answer the phone during normal business hours.**

3. **Responding to questions regarding the foreign establishment's devices imported into the United States.**

4. **Aiding the FDA in scheduling inspections of the foreign establishment.**

5. **Acting as a recipient of information or documents from the FDA when direct contact with the foreign establishment is not possible.**

It is important to note that the **U.S. agent is not responsible for reporting adverse events under the Medical Device Reporting regulation or for submitting 510(k) Premarket Notifications**.

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