STREICHENBERG

Swiss authorized representative

What must be considered in the agreement with the authorized representative in Switzerland?

Foreign manufacturers must appoint an authorized representative who is established in Switzerland. This obligation applies equally to manufacturers from the European Union and overseas. The appointment of a Swiss authorized representative requires a written agreement ("mandate"). The following points must be addressed in the written agreement between manufacturer and authorized representative:

1. **Subject matter of the agreement:** The products or the product categories covered by the agreement must be specified in the annexes. It is permissible to conclude different agreements per product or product category.

2. **Obligations of the parties:** A clear delineation of responsibilities between manufacturer and authorized representative is vital, also in view of civil and criminal liability. Certain services are inherent to the manufacturer, and his performance may not be delegated to the authorized representative. Care must be taken to ensure that the agreements do not deviate from the mandatory allocation of responsibilities.

   Furthermore, the agreement should not be limited to a mere list of obligations incumbent on the authorized representative, such as the verification of the declaration of conformity, the technical documentation or - if required – the certificate of conformity. These obligations arise directly from the law. Rather, the modalities of these mandatory obligations must be specified in detail to implement them into practice.

3. **Warranty:** The authorized representative must meet certain professional and organizational criteria. Consequently, he must guarantee the manufacturer that he will fulfill and maintain these requirements for the entire duration of the cooperation.

4. **Liability:** The agreement must address the liability in the internal relationship between authorized representative and manufacturer; in particular, it must be regulated as to who must bear the responsibility for the damages and the conditions under which the manufacturer must reimburse the authorized representative, including legal costs.

5. **Procedure in case of (negative) incidents:** The agreement must lay down a procedure for handling incidents. Terms such as "incident," "serious," "recall," etc.

must be precisely defined and explained with examples specific to your products. In the event of an incident, annexes should include work instructions on who must do what, in what way, and how quickly. As they are quicker to understand than longer texts, flowcharts are useful for this. The instructions should be country-specific; Swiss requirements differ from those of EU member states, as do the authorities that need to be informed. Finally, the training of those involved must also be addressed, and the procedure should be practiced using concrete examples.

6. **Documentation and reporting obligations:** The agreement must regulate the modalities on storage, confidentiality, and disclosure. The documents made available to the authorized representative must be claimed as confidential. Any exceptions to the confidentiality must be addressed, in particular with regard to the statutory disclosure obligations towards the authorities.

7. **Termination:** If the manufacturer violates his obligations, the authorized representative is not only entitled but also obliged by law to terminate the agreement and notify the authority accordingly.

   Due to the far-reaching effects of a termination, its modalities must be contractually regulated. This includes the question of whether the authorized representative is obligated to request that the manufacturer remedy the legal defect under threat of termination, unless it is to be expected from the circumstances that the defects will not be remedied. Also to address is the question whether the authorized representative must exercise his termination rights immediately and whether he forfeits his rights by excessive waiting.

8. **Choice of law:** In relation to the manufacturer, the authorized representative provides the characteristic contractual services. He is domiciled in Switzerland and performs his services vis-à-vis Swiss authorities. Accordingly, the application of Swiss law appears appropriate. Even if the European Union should have regulated his duties similarly to Switzerland, the authorized representative cannot be expected to take foreign law into account in the performance of his duties.

9. **Jurisdiction:** The agreement must stipulate which court is competent for deciding on legal disputes among the contractual parties. With a jurisdiction clause, the parties exclude the risk of having to settle their disputes in an "unfavorable" venue.

Streichenberg advises companies with regard to the measures to be taken due to the new regulation of medical devices in Switzerland and in relation to the European Union. These recommendations are a free service provided by Streichenberg Attorneys at Law. The suggestions do not replace individual legal advice as each contractual relationship is different.

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