Polmed.de *cooperates with many companies from Russia and the countries of the former Eastern Bloc. We offer you many years of experience in the field of services as the Authorized Representative.*

What Polmed.de provides

- we represent our clients before the European Commission and National Competent Authorities;
- we supervise the product, monitor accidents appearing as the result of using the medical device (Incident Reporting) and we present Advisory Notices;
- we register the products at the EU Authorities;
- we verify and classify the product;
- we assist to implement quality systems which are proper for your products;
- we fulfill a function of „Safety Officer" in Germany and other countries;
- we give advice on the technical documentary's being in accordance with the basic requirements, we label and make risk analysis;
- we store your Declarations of Conformity and your technical documentation to make them accessible to EU Authorities;
- we notice changes in the European law and we create strategies which let your company adapt to it.

Polmed.de

Vertretung und Repräsentanz

We invite You to cooperate!

Contact Us:

Dipl.- oec. Boguslaw Karcz – Director

Boguslaw Karcz (German, Polish)
e – mail: info@polmed.de

Beata Rozwadowska - Assistant director

B.Rozwadowska (English, Russian, Polish)
e – mail: beatarozwadowska@polmed.de

Office:

Phone.: ***+49 711 528 532 79***
mobile phone.: + 49 171 388 0960
e - mail: ***info@polmed.de***
web : ***www.polmed.de***

Polmed.de
Dipl.-oec. Boguslaw Karcz
Steinacker 5
D - 73773 Aichwald

Polmed.de

Vertretung und Repräsentanz

European

Authorized Representative

Polmed.de is a German company that offers consulting services on quality and legal compliance for international manufacturers of medical devices and diagnostic products in vitro. Our company deals with issues related to the quality management system, legal regulations, product documentation, the process of accreditation, certification CE, as well as services in the field of EU representation for manufacturers of medical devices

as the European Authorized Representative

according to the requirements of the medical devices MDD 93/42/EEC, Directive for active implantable medical devices and Directive AIMDD90/385/EE medical devices in vitro IVD 98/79/EC.

Polmed.de *is ready to take on the responsibilities of your Authorized Representative in the European Union, in accordance with Directives MDD and IVDD. Our comprehensive and high quality services ensure a CE mark of conformity with the requirements of the directives.*

„CE" Marking Your "Passport" to the EU Market.

The medical devices directives **(90/385/EEC, 93/42/EEC and 98/79/EC)** require medical device manufacturers to assess the conformity according to the requirements stipulated in the above directives.

The aim of the conformity assessment is to achieve the CE marking and thus to prove the marketability in the European Union.

Since 1998 CE-Mark is required on all medical devices marketed in Europe. The CE-Mark is a proof of compliance with so called "Essential Requirements" of the Medical Device Directive.

For manufacturers **outside the EU**, this means that:

to be placed on the market in the EU, it's a legal requirement that your product must bear a CE marking.

The CE marking will open the borders of all member states of the European Union.

CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations.

The European Union decided to make the unification of standards of production and quality of the products throughout the EU.

As a consequence, standards on ISO 9001 and ISO 13485 quality management, as well as evaluation criteria in the form of the unified procedures are entered in all territory of the European Union.

CE marking on a product:

- Indicates to governments that the product can be legally sold within the European Union (EU) and the European Free Trade Area (EFTA)
- Ensures the product can move freely throughout the European Single Market
- Indicates to customers that the product meets designated minimum safety standards and therefore a minimum level of quality
- Enhances product credibility
- Leads to improved sales and greater customer satisfaction

Polmed.de *as the Authorized European Representative, bears responsibility that your products conform to all actual legal requirements of the European Union and has a wealth of experience in helping companies to attain CE marking for their products.*

What is a EU/EC European Authorized Representative?

EC REP

Non-European manufacturer of medical devices

must designate an EU/EC European Authorized Representative (Authorized Representative)

in order to meet certain requirements under the European Medical Directives:

- Medical Device Directive **(MDD) 93/42/EEC - article14, point 2**
- Active Implantable Medical Device Directive **(AIMDD) 90/385/EEC - article10, point 3**
- In Vitro Diagnostic Medical Device Directive **(IVD) 98/79/EC - article 10(a), point 2**

An Authorized Representative *is the primary contact point for the European Commission and the National Competent Authorities.*

The Manufacturer is required to provide access to the technical documentation and to attach his Authorized Representative's address to the description of the product.

Manufacturer sales representatives (such as importers, authorized sales, authorized distributor) should not be confused with the Authorized Representative within the meaning of New Approach directives.

TASKS AND RESPONSIBILITIES OF AUTHORIZED REPRESENTATIVE MUST BE LISTED ***IN WRITTEN FORM****.*

The Manufacturer of Medical Devices and the Authorized Representative must understand and take a note of the representative's duties and responsibilities BEFORE they assign the agreement.