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Introduction of the international quality management system: OncoTherm Group

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Introduction: The most important aspect for the Oncotherm Group is that our medical devices are prepared according to the concerning international standards and fulfill the inquiries of our customers.
These standards are the followings:

- ISO 9001:2008 Quality Management Systems. Requirements
- ISO 13485: 2003 Medical Devices. Quality Management Systems. Requirements for regulatory purposes
- 93/42/EEC MDD (Medical Device Directive)

Method: I would like to introduce the organizational structure and processes of Oncotherm Group and the requirements which should be adapted (see above).
The Oncotherm Group consists of two parts: the Oncotherm Kft, which is in Hungary and the Oncotherm GmbH, which is in Germany, but these two firms are one unity. They are working together and they have got common quality management systems.
The research, design and development, and the manufacturing are in Hungary, but the marketing, sales, costumer service and service activities are in Germany, so these two parts create one well operative company.

The Company-Group is a marketing method (Oncothermia Method, OTM) which is in synergy with the devices (Oncothermia Device, OTD) and integratively presented on the market as Oncothermia System (OTS). This unification of the German medical and constructive knowledge with the general European manufacturing culture based on European Medical Device Directive and ISO standards. Oncotherm does not follow the practice of the large globalized German companies who are transferring the manufacturing outside Europe. We do everything in Europe and proud on that high level production culture which is represented by our 21 years old company.

Summary: Our devices are prepared by team-working of Hungarian and German highly qualified specialists.. This is the basic of our recent approval by TUV Product Service (TUV SUD, Munich) that our devices are: "Product of Germany, Made in EU".