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Medical devices in Europe are safe, effective, and efficient

BVMed, the German Medical Technology Association, takes a stand regarding the safety of the European medical devices certification procedures

Authorized translation of the BVMed Press Release N° 77/13 of 15 October 2013
www.bvmed.de/medizinprodukte

POLYTECHinformed® is a service offered by:

POLYTECH Health & Aesthetics GmbH
Altheimer Str. 32 | 64807 Dieburg | Germany

Tel. +49 (0)6071 98 63 0
Fax +49 (0)6071 98 63 30

eMail: info@polytechhealth.com
www.polytech-health-aesthetics.com

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Berlin. “Few are the people who know that medical devices have to undergo extensive technical testing before they can be investigated in clinical studies and eventually applied to the patient. New types of pacemakers are, for example, tested for almost 40,000 hours until they have passed all required examination. The respective test documentation is then made available to the Notified Body,” explains Joachim M. Schmitt, Managing Director and Board Member of the BVMed, the German Medical Technology Association.

The requirements for market approval of medical devices include a risk analysis and risk assessment to verify their safety. The devices also have to go through a clinical evaluation to prove their efficiency and effectiveness. Eventually, a comprehensive quality management system has to be applied during their manufacturing process. Depending on the potential risk, type and duration of a medical device application, different risk classes with differentiated examinations and controls apply.

At the beginning of the process we have a risk analysis, which compares the benefits of the product to its possible risk potential. An extensive set of rules defines the assessment parameters for the analysis. Many laboratory tests and a clinical evaluation are necessary to ensure the best possible safety and effectiveness of a medical device before it is applied in a patient for the first time.

Example 1, joint implants: For joint replacement implants, there are numerous specific test standards – a total of 13 standards for hip implants, 8 for knee implants, 6 for spinal implants, and 9 for trauma implants in traumatology. The test standard for stress and wear of hip replacement implants includes, for example, 5 million stress cycles for the prosthetic head and 10 million cycles for the intersection between neck and stem of the hip prosthesis. Some of the manufacturers voluntarily run some 15 million cycles. This wear testing of hip replacement prostheses is performed by specifically designed equipment, for which the standards set various parameters, such as force development, maximum force, test frequency, angle, rotation, test temperature, and number of stress cycles.

Example 2, pacemakers: The extent of documentation required for a cardiac pacemaker system is defined by the European Directive for active implants (90/385/EEC), special standards, the requirements of the Global Harmonization Task Force (STED = Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices), and special requirements of the Notified Body. The internal test peri-

od for a pacemaker system is approximately 40,000 hours. At the end of the test series, the technical documentation amounts to 7 document folders.

Apart from the technical security, manufacturers have to prove the clinical performance and the acceptability of the benefit / risk ratio in a clinical evaluation. For all implantable medical devices and Class III products, clinical trials have to be carried out, unless the use of existing clinical data is sufficiently justified. Conducting clinical trials of medical devices is based on the same requirements as valid for the pharmaceutical sector.

BVMed‘s conclusion: "The current regulatory framework for medical devices is absolutely sufficient to enable manufacturers to produce safe, efficient, and effective medical devices and to place them on the market. Medical devices are safe, efficient, effective, and have to benefit the patient." It is undisputed, however, that the European legal framework for medical devices also has weaknesses. "Therefore, BVMed is committed to improving the designation and monitoring of Notified Bodies, as well as optimizing the vigilance applicable to the manufacturers and market," closes Schmitt.

To illustrate the effectiveness of the existing procedures, BVMed published an infograph on "The long way of a medical device from the idea to the patient". It shows how medical devices are developed, technically and clinically tested, certified and, once approved, controlled. Currently this graph is only available for download in German, translation is in progress. (www.bvmed.de/medizinprodukte)

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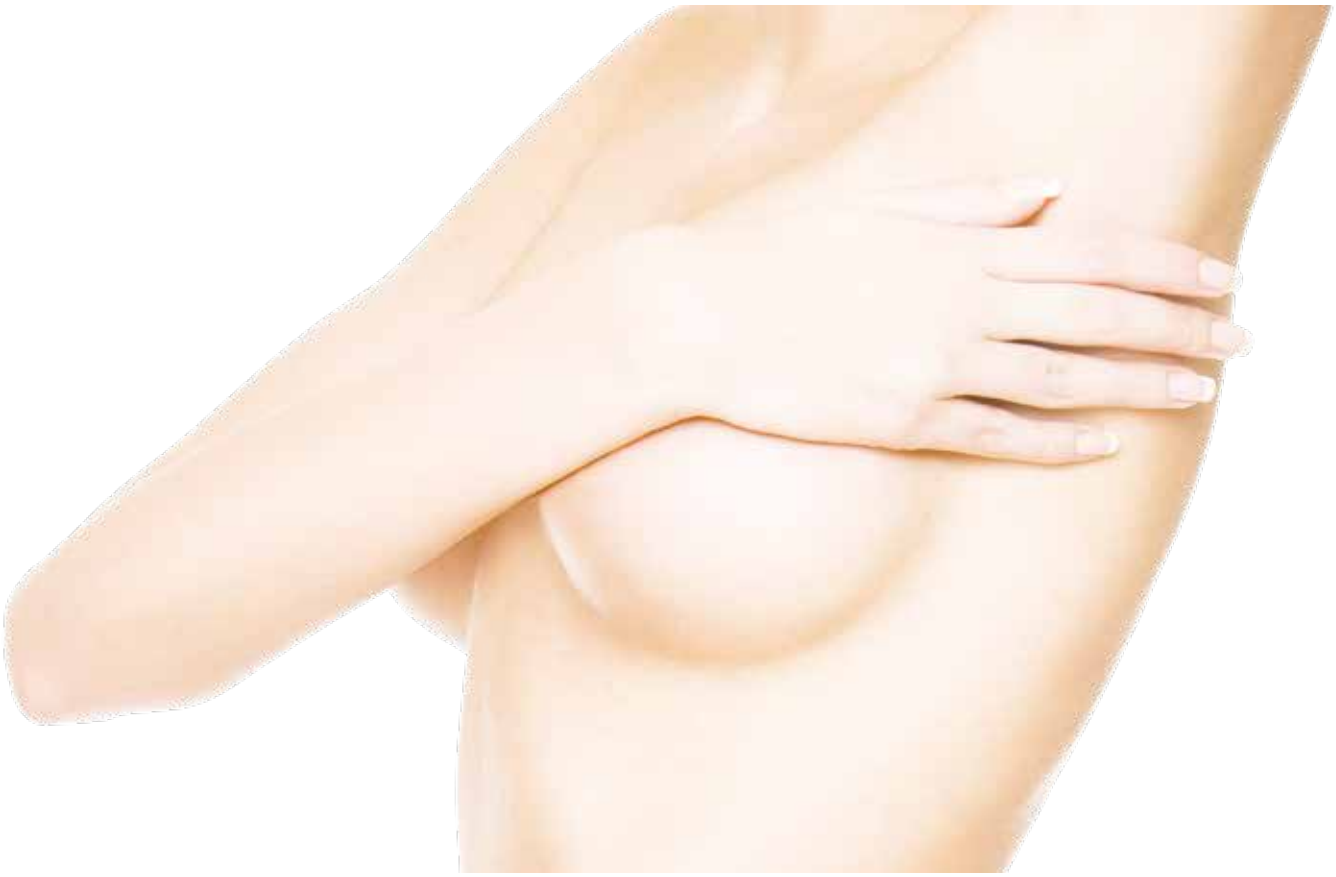

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