



In the Pursuit of Safety:  
Breast Implants

"Made in Germany"

**POLYTECH**   
health & aesthetics

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# Quality made in Germany

German brands enjoy the highest reputation worldwide for superior quality and high-level processing. POLYTECH Health & Aesthetics, the only German breast implant manufacturer, has implemented extensive safety test procedures and guarantees that it adheres to the highest quality standards.

The raw materials we utilize for the shell and gel of our implants are certified for long-term implantation. At our production site in Germany, implants are examined after each production stage to prevent possible errors or defects. The implant is released for sale only when all tests and security checks are passed successfully. In this manner, we consistently ensure high quality and safety for the surgeons and patients.

## German standards

POLYTECH Health & Aesthetics is one of the leading implant manufacturers in Europe and has a history of 25 years of breast implant experience. The company is the only German manufacturer of soft-tissue implants. The premises are located in Dieburg (near Frankfurt), and since July 2008, all implants have been exclusively produced in Germany. Concentrating the production in Germany assures high quality in all areas, increases flexibility and reduces development cycles.

## German focus

POLYTECH Health & Aesthetics was the first company to receive C€ Mark for their implants in 1995. In 2003, the European Community decided that breast implants were to be classified as medical device class III products, a device class that also includes pacemakers, and heart valves. This means that strict guidelines must be followed in the production of breast implants. POLYTECH immediately received clearance for its products because it had previously implemented

quality standards equal to those valid since the 2003 breast implant reclassification into its production as early as 1995 – i.e. much earlier than any other implant manufacturer.

POLYTECH Health & Aesthetics carries the largest product range in the breast implant market with more than 1,500 implant types, both for augmentation and reconstruction. We focus mainly on breast implants for women. In addition, pectoral implants for men as well as implants for the nose, the chin, the calves, and the gluteus are offered.

# Questions & Answers about the

## Safety of Breast Implants



## – Part I – Raw Materials

### ▶▶ Where does POLYTECH Health & Aesthetics obtain the silicone used in its implants?

All silicones used for manufacturing implants at POLYTECH Health & Aesthetics are certified for long-term implantation. They are of the highest medical quality. Worldwide, there are only two companies that produce these silicones: Applied Silicone Corporation and NuSil Silicone Technology. Both are located in California. They have had their silicones tested and registered for this purpose by the FDA. The respective documentation is available to the European Notified Bodies (see p.20).

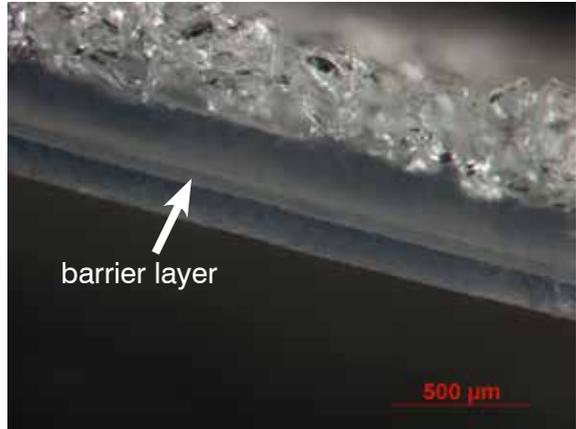
### ▶▶ What can cause a higher frequency of implant shell rupture and silicone bleeding?

To answer this we have to go to the molecular level.

The physically correct term for „bleeding“ is „diffusion“. In the following section you will find a short explanation of what happens during diffusion.

Within the context of breast implants, diffusion means that certain low-molecular-weight silicones of the gel migrate into the shell and then diffuse through the shell. To prevent these very short silicone molecules from passing through the shell and invading the tissue, there are two strategies:

1. One strategy is to chemically design the shell in such a manner that the low-molecular silicone particles cannot pass through. This is achieved by applying a barrier layer. This layer consists of a special silicone that does not allow the particles to migrate through the shell. Theoretically, the barrier layer could be applied directly to the inside or outside of the shell. At POLYTECH Health & Aesthetics we embed the barrier layer between two other layers of „normal silicone“, this is called the sandwich method. These layers increase the shell stability.



In the chemical and/or physical processes described here there is no definite yes or no (i.e. not 0% or 100%). If we say that the silicone particles cannot pass through the barrier layer, it means that the migration rate is greatly reduced compared to that rate in „normal silicones“ – but it is not absolutely zero.

2. Another strategy is to remove the low-molecular silicone particles from the raw silicone by applying special purifying procedures. These procedures are extremely complex and costly. The raw silicone for the gel filling that is produced in this manner is extremely pure. This is why these silicones are more expensive than simple industrial silicones.

All reputable manufacturers of breast implants combine both strategies in order to avoid bleeding as much as possible.

If a manufacturer used industrial silicone for the gel filling instead of the implantable silicone, it might be possible that the second strategy to avoid bleeding would no longer work and more bleeding could be the result.

Industrial silicone that is not sufficiently pure may also be an explanation for a higher rupture potential of an implant shell. This would be due to the fact that the small silicone particles that migrate into the shell would lead to a „swelling“ of the shell. The more particles migrate into the shell, the stronger the swelling. The swelling stunts the mechanical properties of the shell and would be a possible explanation for a higher shell rupture rate.

## – Part 2 –

# Testing and Quality Control

The future product quality is defined by the decisions taken in the development stage. To set the course correctly, the following questions should be answered:

- ▶ Which raw materials should be used?
- ▶ How can the highest possible mechanical and biological safety be obtained?
- ▶ What actions guarantee the highest product stability without reducing the functionality?
- ▶ What strategies should be followed to reduce known complications as far as possible?
- ▶ What shape should the products have so that the surgeon will achieve optimum aesthetic results?
- ▶ How should the production process be structured in order to comply with the requirements and to avoid potentially weak spots right from the start?

Of course, this is just a very small and illustrative excerpt from a possible list of questions. Many of the other questions to which answers have to be provided in order to guarantee the safety and effectiveness of the products are dictated by the rules and regulations applicable to the certification of medical devices. The better the preparations, the better the final product quality.

The applicable rules and regulations, in particular the Breast Implant Standard EN ISO 14607, require an evaluation of the mechanical, chemical, biological and clinical safety of the products based on test results. The Standards for the Quality Assurance System, EN ISO 9001 and EN ISO 13485, demand a safe production process with a special focus on critical processes.

A general example is the sterilization process. A product-specific process is shell manufacturing.

We perform both, internal and external tests.

- ▶ External tests are executed by independent test laboratories. Their results serve as an impartial proof that the products comply with the requirements. These tests include the testing of the mechanical stability, biocompatibility and regular tests to verify product sterility.
- ▶ Internal tests as described below are performed on an ongoing basis.

All actions and resulting solutions are compiled in a Technical Document that is submitted to a Notified Body for verification (details see Part 3 of this brochure). If this institution approves the documentation and procedures, it will allow the manufacturer to place its product on the market.

Below you will find some examples for the internal tests performed by POLYTECH Health & Aesthetics.

### ▶▶ How do you ensure that the implants are biologically compatible?

The biological compatibility of breast implants is ensured on two levels:

1. All raw silicones that can be used for long-term implantation must go through a series of biological tests.
2. Additionally, finished implants are tested for biocompatibility.

The international standard ISO 10993 dictates which tests must be executed and how they are to be performed. Additional tests

according to the U.S. Pharmacopeia (American rules and regulations for pharmaceutical products and medical devices) are likely to be performed as the manufacturers of the silicone gel are American companies.

- ▶▶ How does POLYTECH Health & Aesthetics ensure that the implants resist the mechanical forces during the implantation surgery and in the body for the years after?

Before and after the filling of the implants various shell tests are performed:

- ▶ Directly after shell manufacturing, when the shells have been removed from the moulds, every shell is tested for thickness and weight.



The maximum and minimum shell thickness are ascertained via approximately 10 measurements in three areas: the front (anterior), at the edge (equatorial), and the back (posterior). The results are checked for compliance with the specifications for implant shells. The weight is also an indicator of the thickness and regularity of the shell. Only shells that comply with the specifications proceed to the next step in the production process.

- ▶ After the testing of the thickness and weight, the shell is checked visually for defects and irregularities.
- ▶ Simultaneously, representative shells are selected daily from the production cycle and undergo destructive testing. Some of these

tests are required by the Breast Implant Standard. Specimens are punched out of the selected shell and are subjected to tensile testing. One of these tests measures what forces are necessary to make a specimen rupture after it has been damaged by a standard cut. A non-damaged specimen from the test shell is tested for its elongation until rupture, and a third is checked for its ability to return to its original shape after a standard elongation without wearing out. Just to give an example: the maximum elongation according to the standard has to be 450%, our shells achieve an average elongation of 950%, which is twice the required value.

With these tests we simulate the forces the implants are subjected to during implantation surgery. Just as with the tests described above, the lot from which the test shell had been selected only proceeds to the next step in the production process if all specimens have successfully passed the tests. This is a 100% control as one test shell is selected from every lot.

- ▶ An integral part of the shell is the patch which closes the opening at the back of the shell created during the production process: the mould of the shell is mounted on a mandril and that is fixed to the workbench. The spot where the mandril is linked to the mould creates the opening. The patch is punched out from silicone sheets that are produced in the same way and have the same structure as the shells. These sheets undergo the same testing as the shells. The resilience of the connection between the patch and the shell is examined with tensile tests on representative specimens picked



out daily from the production. Per patch lot one patch is picked for testing, thus 100% of all patch lots are tested. Of the patch tests performed by POLYTECH Health & Aesthetics only some are required by the Breast Implant Standard; we perform additional tests on the patches and the shells.

- ▶ Before the patch is attached to the shell and prior to the filling of the implants with silicone gel the products undergo several small production stages. Every employee who takes over a semi-finished product in order to perform another step in the process will check the product forwarded to him. He will only process it if it complies with the specifications. This checking consists of visual controls for defects and irregularities. Once the employee has finished his task he will again check the product. He will only forward it to the next production step if it complies with the requirements. The next in line in the production cycle will apply the same checking procedure. As every product passes through 5 to 10 production steps it will be checked 10 to 20 times in addition to the destructive tests described above.



- ▶ After the attachment of the patch, the shell is filled with silicone gel and vulcanized. The vulcanization will make the gel cross-link, producing the semisolid, cohesive consistency that is state of the art. Before being packed for sterilization, every implant is then checked in a final control. The criteria for the check are weight, irregularities, defects and damages, attachments/contamination, the stability of the connection between shell and patch. Then the implants are boxed in transparent blister packages and sterilized.

- ▶ After sterilization and before the products are packed into the final cartons they are checked visually once more – one of the reasons why we use transparent sterilization packages. In this check we examine the packaging according to criteria ensuring that the sterility of the products is guaranteed for a minimum of 5 years. We also check the surface of the implants for contamination and verify that no bubbles developed during the sterilization procedure.
- ▶ The quality of the sterilization is tested in special microbiological procedures. These tests are performed externally, by an independent test institute (Institut SGS Fresenius, Taunusstein, Germany).

Additional tests that we regularly perform on finished implants are described in the following.

▶ **Fatigue test**

In this test we check the dynamic forces working on the breast implants in the chest of a jogging woman. According to the Standard, 2 million cycles are required. This corresponds to a weekly mileage of 10km over a period of 10 years. The shell may not show any defect after this test. We do up to 36 million cycles with our implants remaining intact. This corresponds to a weekly mileage of 180km over a period of 10 years (more than 4 marathons per week) or a weekly mileage of 10km over a period of 180 years.

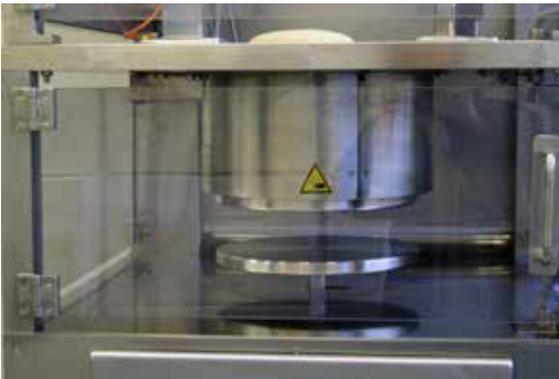


► **Impact test**

A weight of 4.4kg drops free fall on an implant from a standard height. The forces working on the implant correspond to the impact created by the safety belt on an implant when a woman hits a wall in a car riding at 45km/h without using the brakes. Our implant shells resist these forces unharmed.

► **Static rupture test**

The implant is put in between two compression plates and slowly subjected to an increase in pressure until it ruptures. Typical values achieved are 500kg and more – much more than a human body would stand without damage.



►► What is the thickness of an implant shell?

The thickness of the shell depends on the type of implant.

Implants with a textured surface have a thickness of 0.7 +/- 0.2mm.

## – Part 3 –

# Registration, Certification, and Regulatory Surveillance

- ▶▶ Who grants POLYTECH Health & Aesthetics their CE Mark? and
- ▶▶ What certification procedure is followed by POLYTECH Health & Aesthetics?

A company's right to use the CE Mark for their products is the result of their having passed a Conformity Assessment Procedure (certification procedure). This procedure is audited by a Notified Body (p.20). The Notified Body responsible for POLYTECH Health & Aesthetics is MDC – Medical Device Certification GmbH.

The certification procedure that we apply to our breast implants (and our other implants) is conform to Annex II of the Medical Device Directive 93/42/EEC including Section 4.

Admittedly: these answers are only helpful for medical devices specialists handling regulatory affairs. In the following you will find some information on certification procedures for non-specialists. In order to make things understandable some issues were simplified, but please be aware of the fact that this is still quite a complex issue.

- ▶▶ How is a breast implant certified?

This question is not easy to answer. For a correct reply it is necessary to look into the European Medical Device Directive and to clarify some terms.

1. Breast implants are not pharmaceutical products; but medical devices.
2. The term registration only applies to pharmaceutical products. Medical devices are certified (in Europe).
3. In Europe, the certification procedure for medical devices is ruled by the Medical Device Directive 93/42/EEC. This Directive has to be converted to national law by each member of the European Union. In Germany, this was realized in the Medical Device Act.

Generally, a certification procedure runs as follows:

Before a manufacturer of a medical device can place his product on the market in Europe, it has to undergo a Conformity Assessment Procedure (p.19).

- ▶ The Conformity Assessment Procedure has to prove that the Essential Requirements (p.18) are fulfilled.
- ▶ Once this proof has been provided, the manufacturer may use the CE Mark for the product and is free to place the product on the market.

As soon as it is established that a product is a medical device (breast implants are definitely medical devices, see article 1 of the directive), the risk class (p.22) for the product has to be ascertained.

The risk class determines which Conformity Assessment Procedure has to be applied (see article 11 of the Directive). All in all, there is a total of 5 different Conformity Assessment Procedures (Annexes II to VII). These can be applied apart or in combination, depending on the risk class.

Breast implants are assigned to risk class III (for details regarding the risk classes see p.22). Manufacturers of class III products may apply

two of the Conformity Assessment Procedures. Due to the product qualities and the manufacturing process the Conformity Assessment Procedure applicable to implants is the procedure according to Annex II (EC Conformity Declaration – total Quality Assurance System).

POLYTECH Health & Aesthetics and according to our knowledge all other reputable implant manufacturers apply this Conformity Assessment Procedure. This is indicated in the EC Certificate that every manufacturer will submit to his clients on request. A Notified Body has to participate in this Conformity Assessment Procedures for all medical devices assigned to risk classes higher than I.

### ▶▶ What are the "Essential Requirements"?

In Annex I of the Medical Device Directive you will find the list of the so-called Essential Requirements that a medical device has to fulfill. Due to the nature of a directive that applies to a large range of products (for example, medical adhesive tape, hospital beds, anesthetic devices, implants, etc.), the Essential Requirements are kept broad.

Generally, a medical devices manufacturer needs to prove that his product is safe and that it effectively fulfils the function for which it is designed.

The Essential Requirements are substantiated in standards and other technical rules and regulations. There are standards for a wide variety of fields that may play a role in a Conformity Assessment Procedure. Examples include:

- ▶ Products (like breast implants)
- ▶ Procedures (like sterilization, packaging)
- ▶ Testing (like biological safety, clinical safety)
- ▶ Quality assurance

- ▶ Risk management,
- ▶ Production facilities (like clean rooms), and
- ▶ Labeling and instructions for use.

Once all applicable standards – a considerable number – have been complied with, the product is conform to the Essential Requirements and the CE certification can be granted.

If available, it is important that the manufacturers revert to so-called harmonized standards. Harmonized means that they have been approved by the respective advisory boards of the European Commission. Since medical devices are in constant development it is not possible to find a harmonized standard for all products. However, EN ISO 14607, the Standard for Breast Implants, is harmonized.

### ▶▶ Can you provide an example of a Conformity Assessment Procedure?

A medical devices manufacturer will use the list of Essential Requirements to identify all applicable standards relevant to the product. They will then prove that all requirements of the standards are fulfilled. Depending on the risk class of the product one will have to apply special Conformity Assessment Procedures under audition of a Notified Body. This is ruled by the Medical Device Directive Annexes II to VII.

The following list specifies typical, product-specific fields that have to be assessed regarding their conformity with the requirements. This assessment is performed by checking collected data and test results.

- ▶ Mechanical stability and safety
- ▶ Chemical and biological safety
- ▶ Clinical safety
- ▶ Effectiveness (Does the product fulfill the functions the manufacturer says it provides?)

Proofs furnished by the manufacturer regarding their organization and production process provide answers to the following questions:

- ▶ Has the manufacturer installed a Quality Assurance System and has its functionality been proven (acc. to EN ISO 13485)?
- ▶ Has a risk analysis been performed regarding the potential risks
  - of the product design?
  - of the production process?
  - of storage and transport?
  - of the product application?Have all identified risks been reduced to a justifiable level?
- ▶ Are all critical processes of the production, packaging, sterilization, etc. mastered?
- ▶ Does a functioning vigilance system exist? Are incidents reported correctly to the surveillance authorities? (In Germany, this is the BfArM, the Federal Institute for Pharmaceutical Products and Medical Devices.)

If all applicable standards are complied with, the product is conform to the Essential Requirements and the CE Certification will be granted.

The medical devices manufacturers have to document all tests, proofs and actions in a Technical Documentation and a Quality Assurance Manual.

## ▶▶ What is a "Notified Body"?

The Notified Body is the institution trusted with the audit of a medical devices manufacturer. The manufacturer has to prove that his product fulfils all requirements as described above to this institution; they will verify the product's conformity with the Essential Requirements.

Once conformity has been established, the Notified Body will issue the respective EC Certificates – which very often are incorrectly referred

to as CE certificates. Then, the manufacturer may apply the CE Mark together with the number assigned to the Notified Body to his product (see below).

Notified Bodies may be national authorities, but most are private companies. Every Notified Body has a particular number that has to be shown together with the CE Mark on the product.

The Notified Body responsible for POLYTECH Health & Aesthetics is the private company MDC Medical Device Certification GmbH (Notified Body n° 0483). Other known German Notified Bodies are the TÜVs (Technical Surveillance Societies): TÜV Nord (0044), TÜV Süd (0123), TÜV Rheinland (0197). Contrary to their appearance these societies are private companies. An example for a national Notified Body is the Portuguese INFARMED (0503).



In case they are not a national authority, the Notified Bodies are appointed, controlled and accredited by national authorities. The German authorities responsible for the Notified Bodies are the ZLG (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten : Central Department of the German States for Health Protection Regarding Pharmaceutical Products and Medical Devices) and the ZLS (Zentralstelle der Länder für Sicherheitstechnik : Central Department of the German States for Safety Engineering).

The ZLS is only responsible for Notified Bodies that are authorized to certify active medical devices (active means that they are powered by an internal or external source of energy). The Notified Bodies authorized to certify medical devices are published by the European Commission; the respective list may be found on the internet (see links p.30).

From our point of view, we consider it mandatory that a medical devices manufacturer finds a Notified Body that possesses expert

knowledge regarding the medical devices they are intended to certify. This is the only way to ensure that the products will have optimum effectiveness combined with maximum safety. In 1994 POLYTECH Health & Aesthetics expressly chose MDC, a Notified Body that disposes of the required expertise for our products as they are knowledgeable regarding the Medical Device Directive and silicone technology. Since then, this decision has proven its worth to us, our partners and clients.

## ▶▶ What are risk classes in the context of medical devices?

The different groups of medical devices are assigned to four risk classes. The higher the class, the higher is the risk allocated to the medical device when applied. The four risk classes are numbered as follows: I, IIa, IIb, III. A product is assigned to a risk class according certain criteria if fulfils. A typical cascade – very much simplified – is described in the following:

### **Class I:**

The product will only come into contact with intact skin. Examples: support stockings, compression bandages.

### **Class IIa:**

The product will come into contact with an open wound or will be inserted surgically in the body for a short period (less than 30 days). Examples: special catheters, canulas.

### **Class IIb:**

The product will be implanted surgically in the body for a longer period (more than 30 days). Example: implants.

### **Class III:**

The product will be implanted surgically in the body for a longer period (more than 30 days) and will come into direct contact

with the central nervous system (i.e. brain, spinal cord) or the cardiovascular system (i.e. heart, aorta). Typical examples: cardiac valves, electrodes implanted directly in the brain.

The rules according to which the medical devices are assigned to the respective risk classes are listed in Annex IX of the Medical Device Directive.

Corresponding to these rules, breast implants are class IIb products. In 2003 however, a special directive (2003/12/EC) was passed that assigned breast implants to risk class III. One might question whether this equation with „real“ class III products is medically justified. In this context it should be noted that comparable products for other body regions and for men are still class IIb products (examples: calf implants, pectoral implants, testicular implants).

All Conformity Assessment Procedures of class IIa, IIb and III products have to be audited by a Notified Body. This is indicated by the number that is combined with the CE Mark and affixed to the product.

The meaning of this breast implant reclassification can be derived from Annex II, Section 4, of the original directive in which the Conformity Assessment Procedure is described. Annexes II to VII generally rule the audit intensity the Notified Bodies have to apply. The higher the risk class, the more intensive the audits will be and the less tolerant the regulatory surveillance. No Notified Body needs to participate in class I product exams. For class III products, a so-called design examination has to be performed by the Notified Bodies. The way this has to be effected is described in secondary rules and regulations.

Simply put, since the 2003 reclassification the technical requirements regarding the products have not changed considerably, but the tolerance the manufacturers were able to apply when interpreting the results has been clarified.

The following example illustrates what this means:

Since 2003, the required minimum elongation of a shell is 450%. This was the same before 2003, but then the test had to be performed with 2 or 3 shells, and even when they barely made it the test was judged as passed successfully. Today, manufacturers have to ascertain that all shells released for sale fulfill the requirement using statistical methods. As not every shell can be tested – the test is destructive –, the test shells have to clearly surpass the 450% requirement. The standard deviation has to remain within tight limits. This is the only way to safely prove that all shells fulfill the requirements and that the production process always supplies shells that comply with the requirements.

Breast implants have been a topic of controversy since the „silicone crisis“ at the beginning of the 1990s. It was then that we at POLYTECH Health & Aesthetics established together with our Notified Body a certification process according to class III requirements for our breast implants. Proceeding thus, we were able to allay the doubts of the surveillance authorities (ZLG, the regional board, and BfArM). This strategy and the associated higher quality requirements applied to our products, procedures and proofs considerably facilitated the 2003 reclassification of our breast implants. We were able to pass the corresponding Conformity Assessment Procedure as early as December 2003.

### ►► How does a Notified Body audit the manufacturer?

Before a product or a quality assurance system is certified by the Notified Body, the latter will study the Technical Documentation and/or the Quality Assurance Manual. It will check whether these documents are conform to the requirements.

Then, the Notified Body will perform an audit of several days at the production site of the manufacturer. During the audit the Notified Body will check all processes and the respective rooms (production areas,

clean rooms, warehouse, etc.). The auditors will control whether the procedures and facilities match the documentation and whether they in fact conform to the requirements. The auditors will verify the complete flow of goods from the raw materials to the finished product. They also verify on site whether the applied processes (order processing, purchasing, production, storage, shipping) are conform to the requirements.

These audits are scheduled once per year. Of course, just as the regulatory authorities (i.e. their regional boards), the Notified Body has the right to check on the company without prior notice at any time if it suspects infringement (p.28).

When a product has been certified according to the Conformity Assessment Procedure described in Annex II for class III products, the Notified Body has to be informed of every relevant modification varying from the documentation and the auditors have to approve the change prior to its realization. This applies to changes in:

- ▶ the production process,
- ▶ the product design, and
- ▶ the raw materials used.

It is the decision of the Notified Body whether it will do an audit on site for such a modification.

### ▶▶ Is the CE Mark a reliable proof for high-quality products?

Among the specialists who are acquainted with the procedures, the CE Mark is a reliable proof for products manufactured according to the relevant standards.

The rules and regulation applicable to medical devices are an extensive, hierarchically structured system. It includes the European

Medical Device Directive as well as standards, guidelines, technical specifications, national laws and regulations, etc. The Medical Device Directive of 1994 (93/42/EEC) is the master document that is kept relatively broad. In order to know which requirements and exams apply the secondary documents have to be studied.

In general, the CE Mark means that the product to which it is attached conforms to the safety and effectiveness required by the corresponding rules and regulations of the respective product group. This general procedure has been established by the European Union for various product groups, such as medical devices, electronic devices, and toys. For all of these, a manufacturer has to prove the conformity to the requirements. Then, the manufacturer may attach the CE Mark to his product.

Some opinion leaders who either have not understood the principle or want to purposely mislead the public have used the application of the same symbol to make an incorrect comparison of the different product groups. As explained above, the required safety proofs within the respective product groups vary considerably depending on their risk class. One cannot equate different product groups and the respective safety requirements just because the same symbol is used. Required certification varies greatly depending on the product type, and to compare them by symbol alone indicates a lack of knowledge of the system and its intent.

►► Does an EC Certificate suffice for examination of medical devices or are FDA-registered products safer?

The European CE certification system has proven its worth. With the reliability of any regulatory system it guarantees that certified medical devices are safe for users, physicians and patients. But any efforts of a regulatory system can be annulled when a criminal mind wants to bend the rules. And any regulatory system can only be as good as the

people who are handling it. Many incidents in the past, which occurred for example in the food industry, pharmaceutical industry or medical device industry, have shown that no regulatory system is perfect and is able to provide 100% safety.

We often hear that an FDA (Food and Drug Administration) registration is better than the CE certification when it comes to quality issues. It has been proven that this is definitely not the case. The study of the independent Boston Consulting Group (see links p.30) demonstrates that the European certification system guarantees that European patients have faster access to newer, more innovative and better medical devices than patients in the USA – and this with at least the same degree of safety. The study proves that the CE certification process is more effective than an FDA registration.

Only the two American companies Allergan and Mentor (J&J) have FDA-registered silicone-gel filled breast implants. In order to understand what this means, we present the following background information:

1. An FDA registration is only required if products are to be sold in the USA. For such registration it is necessary to invest heavily – several years of studies and many millions of US dollars. This means, it is a strategic decision of a company whether it wants to make this investment; it has nothing to do with the quality of their products. For this decision, the company needs to evaluate the future market share they may gain with their product. Those who do not want to market their products in the USA do not need to invest in an FDA registration for them. Unfortunately, the FDA approval of breast implants in the US has become a political decision rather than a scientifically based decision.
2. Since both American companies invested heavily in their FDA registrations they now want to harvest the benefits of their investment and market it as a unique selling point of all their products.

There is no question that a manufacturer has to prove the safety and effectiveness of a medical device to a regulatory institution, be that by an organization like the FDA or a Notified Body. Due to the increasing complexity of the products this can only be ascertained by an open exchange between the manufacturer and the regulatory institution. This is exactly the path that we take with the European system of the CE certification.

▶▶ Is POLYTECH Health & Aesthetics in contact with BfArM, the Federal Institution for Pharmaceutical Products and Medical Devices, or other regulatory authorities?

Apart from the Notified Body the regional board is the executive authority and responsible for any regulatory surveillance actions. Events such as start of operations, the name of the company safety officer, new products placed on the market as well as incidents and near-incidents we have to report to the regional board or directly to the BfArM. The regional board can come to our premises at any time, with or without notice, to check on us.

In the wake of the events concerning a French company, our regional board scheduled an audit with us. It is often said that announced audits are not as effective as audits that are conducted without prior notice. That may be the case if the auditing institution has reason to suspect that a manufacturer is infringing the rules. However, if they want to ascertain whether a manufacturer fulfils its duties correctly or is working sloppily, the institution will be able to prove this anytime. It is impossible for a manufacturer to make good for the months or years in which he has neglected his duties.

▶▶ Are the POLYTECH Health & Aesthetics products recommendable without hesitation for implantation?

Definitely. We have more than 25 years of experience in the breast implant business and can provide comprehensive literature to document the safety of our products. We exclusively utilize materials certified for long-term implantation. Our products are checked scrupulously before and after each step in the production process. In this way, we ensure consistently high quality and safety for the surgeons and patients. We proved our dedication to safety when we launched the warranty program Implants of Excellence for our breast implants in 2007. This program enables us to follow-up on the patients' well-being after they receive our implants.

## Links

### Study of Boston Consulting Group regarding CE certification

<http://www.eucomed.org/newsroom/8/104/EU-regulatory-system-brings-Europeans-fastest-access-to-medical-technology-without-compromising-safety/>

<http://www.eucomed.org/uploads/Press%20Releases/BCG%20study%20report.pdf>

### Medical Device Directive 93/42/EEC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF>

### EC Certificates acc. to Annex II of the MDD 93/42/EEC

<http://www.polytechhealth.info/images/pdf/EC%20Annex%20II%202018-11-12%20en.pdf>

<http://www.polytechhealth.info/images/pdf/EC%20Annex%20II%20Section%204%202018-11-26%20en.pdf>

### Certificate Quality Management System acc. to DIN EN ISO 9001

<http://www.polytechhealth.info/images/pdf/QM%20ISO%209001%202016-10-15%20en.pdf>

### Certificate Quality Management System acc. to DIN EN ISO 13485

<http://www.polytechhealth.info/images/pdf/QM%20ISO%2013485%202018-10-15%20en.pdf>

### Declaration of Conformity

<http://www.polytechhealth.info/images/pdf/Konformit%C3%A4tserkl%C3%A4rung-2011-11.pdf>

### Implants of Excellence

<http://www.polytechhealth.info/index.php/en/2012-12-05-16-45-07/lifelong-warranty>

[http://www.polytechhealth.info/images/pdf/loE\\_Information\\_engl\\_2014-09.pdf](http://www.polytechhealth.info/images/pdf/loE_Information_engl_2014-09.pdf)

### Applied Silicone: Factors in Selecting Medical Grade Silicones

<http://www.appliedsilicone.com/iso-certification/factors-in-selecting-medical-grade-silicone/>

### Nusil: Unrestricted Healthcare Material Selection Guide

<http://www.nusil.com/Products/Healthcare/Unrestricted/Documents/Unrestricted%20Healthcare%20Materials%20Selection%20Guide.pdf>

### List of Notified Bodies in Europe

[http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\\_id=13&type\\_dir=NO%20CPD&pro\\_id=99999&prc\\_id=99999&ann\\_id=99999&prc\\_anx=99999](http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999)

### Standards and regulations mentioned in the text

- ▶ EN ISO 9001
- ▶ EN ISO 13485
- ▶ EN ISO 14607
- ▶ EN ISO 10993
- ▶ U.S. Pharmacopeia

**POLYTECH Health & Aesthetics GmbH**

Alzheimer Str. 32 | 64807 Dieburg | Germany  
phone +49 (0)6071 9863-0 | fax +49 (0)6071 9863-30

eMail [info@polytechhealth.com](mailto:info@polytechhealth.com)  
[www.polytech-health-aesthetics.com](http://www.polytech-health-aesthetics.com)

Implants made by POLYTECH – QUALITY made in Germany 