

POLYTECH Health & Aesthetics gets approval for breast Implants

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POLYTECH sold the three millionth implant since its establishment in 1986. The company is the only German manufacturer and present in over 75 countries worldwide. All implants are manufactured in the company's own production facilities in Dieburg near Frankfurt.

As part of the recertification, the company was granted the CE Mark for POLYTECH and B?Lite® breast implants for another five years in November 2018.

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Wolfgang Steimel, CEO of POLYTECH said, "As the only German manufacturer with over 30 years of market experience, we are one of the leading international companies in the field of development and production of silicone breast implants. The quality of our products and patient safety always have top priority, and we are fully aware of our responsibility at this point."

As early as 1995, the company was one of the first manufacturers in the world to receive CE marking for its products and already followed quality standards for Class III products at this early stage.

With the adoption of the new European Medical Device Regulation (MDR) in May 2017, which must be fully implemented by May 2020, the conditions for the registration of products have already become significantly more stringent. All Notified Bodies must now recertify for the MDR and demonstrate that they meet the stricter requirements. Since 2014, the annual audits have been supplemented by regular unannounced audits.

Wolfgang said, "We have been working with a Notified Body specialising exclusively in medical devices since the introduction of the European Medical Devices Directive in 1994, which was the precursor to the new MDR. In addition, we carry out extensive safety tests with test criteria that significantly exceed the specified requirements of the relevant standards. In addition to the permanent, in-process quality controls of the manufactured implants, randomly selected products are subjected to daily tests and stress tests under extreme conditions. In addition, as part of the CE recertification, a biological

assessment/analysis was performed by an independent specialist institute. Biocompatibility and toxicity testing of the implants also ensure their safety. This is how we live up to our quality standards and have been guaranteeing consistently high quality for over 30 years, thus ensuring safety for the physicians and patients who use and trust our products.”

POLYTECH Health & Aesthetics GmbH was founded in 1986 in Dieburg and today is one of the world's leading companies in the field of development and production of silicone implants. The focus is on breast implants, which are used in reconstructive surgery as well as in aesthetic plastic surgery.