

**EC Design Examination Certificate**  
**EC Directive 93/42/EEC Annex II, Article 4**  
**Medical Devices**

**Registration No.:** ID 60024642 0001

**Report No.:** 21140748 001

**Manufacturer:**

Silimed Silicone e Instrumental  
Médico-Cirúrgico e Hospitalar Ltda.  
Rua Figueiredo Rocha 374 e 494  
21240-660 Rio de Janeiro  
Brazil

**Manufacturing Facility:**

Silimed Silicone e Instrumental  
Médico-Cirúrgico e Hospitalar Ltda.  
Rua Figueiredo Rocha 374 e 494  
21240-660 Rio de Janeiro  
Brazil

**Product:**

Medical Device

Prostheses, Mammary, Internal, Inflatable and Gel-Filled

**Identification:**

Silicone Mammary Implants

Products: see attachment

The EC design examination certificate refers to the above mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of the directive. The manufacturer is entitled to use this certificate with the manufacturer's declaration of conformity.

**Date of Expiry:** 19.09.2009

**Notified Body**

Cologne, 20.03.2009



**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

**TÜV Rheinland**  
**Product Safety GmbH**  
**Am Grauen Stein, D-51105 Köln**

**Attachment to**  
**Registration No.:** ID 60024642 0001  
**Report No.:** 21140748 002

**Manufacturer:** Silimed Silicone e Instrumental  
Médico-Cirúrgico e Hospitalar Ltda.  
Rua Figueiredo Rocha 374 e 494  
21240-660 Rio de Janeiro  
Brazil

**Scope:** Products:

Mammary implants, up to 700 g:

- Gel-Filled with Smooth Surface
- Gel-Filled with Textured Surface
- Gel-Filled with Polyurethane Coated Surface
- Gel-Filled with Irregular Surface
- Inflatable with Smooth Surface
- Inflatable with Textured Surface

Cologne, 27.04.2009

