

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

