

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**POLYTECH  
SILIMED**

EUROPE GmbH

**Alzheimer Straße 32  
64807 Dieburg  
Germany**

for the scope

**silicone implants for body contour correction  
mammary implants, pectoralis implants, testicular implants,  
facial implants, calf implants, gluteal implants, tendon spacers, expanders  
delivery sleeves for implants**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven, that this quality system  
meets all requirements according to

**Annex II – Section 3  
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

This certificate is valid until:	2008-12-02
Certificate registration no:	0008.01.01/0
Stuttgart	2004-02-10



Head of  
Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-976.94.05

mdc medical device certification GmbH  
Kriegerstraße 6  
D-70191 Stuttgart, Germany  
Phone: +49-(0)711-253597-0  
Fax: +49-(0)711-253597-10  
Internet: <http://www.mdc-ce.de>

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith grants

**POLYTECH  
SILIMED**

EUROPE GmbH

**Alzheimer Straße 32  
64807 Dieburg  
Germany**

for the scope

**mammary implants**

**silicone shell**

**(silicone gel filled/salines, smooth/textured,  
single lumen/double lumen)**

**silicone shell with micro polyurethane foam covering  
(silicone gel filled/salines, single lumen)**

the

## EC Design Examination Certificate

The examination of the design of the product by mdc has proven,  
that according to the report of the  
file review no. 0008-001 the design meets the requirements according to

### Annex II – Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid  
mdc certificate according to Annex II – Section 3 for the above mentioned products.

This certificate is valid until:	2008-12-02
Certificate registration no:	0008.11.01/0
Stuttgart	2003-12-02

*M. Maurer*

Head of  
Certification Body



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