

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

Polytech Health & Aesthetics GmbH
Alzheimer Straße 32
64807 Dieburg
Germany

for the scope

**silicone implants for body contour correction:
mammary implants, pectoralis implants, testicular implants,
calf implants, gluteal implants, expanders; delivery sleeves for implants,
sterile and non-sterile silicone gel filled sizers for mammary implants,
pectoralis implants, calf implants, gluteal 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 – excluding Section 4
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.

Valid from	2018-11-13
Valid until	2021-11-12
Registration no.	D1007400031
Report no.	P17-01126-103505
Stuttgart	2018-08-13



Head of Certification Body



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

POLYTECH

Health & Aesthetics

Polytech Health & Aesthetics 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)

(see attachment)

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that 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 – excluding section 4 for the
above mentioned products.

Valid from	2013-11-29
Valid until	2018-11-26
Registration no.	D1007400023
Report no.	E-D10074_2013-11-29
Stuttgart	2013-11-29



Head of Certification Body

