

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



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