

# 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	2019-12-21
Valid until	2024-05-26
Registration no.	D1007400034
Report no.	P19-01168-154095
Stuttgart	2019-12-17



Head of Certification Body

