

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Medi-Globe GmbH  
Medi-Globe Straße 1-5  
83101 Achenmühle  
Germany**

for the scope

**products class IIa:** drainage / sets, aspiration needle for bronchoscopy and gastroscopy, aspiration needle for ultrasound endoscopy, injection needle, fibrin needle, extraction bag, dilation balloon

**products class IIb:** hot biopsy forceps, high frequency handle for hot biopsy forceps, polypectomy snares, sphincterotomes, high frequency handle for polypectomy snares and sphincterotomes, pancreatic stents / sets, biliary stents / sets, glycojel wound dressing and catheter fixation system with glycojel wound dressing

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	2011-06-22
Valid until	2016-06-22
Registration no.	2434.15.01/0
Report no.	E 2434.15 / 2011-06-10
Stuttgart	2011-06-10



Head of Certification Body

