

# EC Certificate of Conformity

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Medicel AG  
Dornierstrasse 11  
9423 Altenrhein  
Switzerland**

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

**Effective date: 2020-01-15**

**Expiry date: 2023-07-26**

Report No.: 2073FS20F

Process No.: QS – 2073

Certificate No.: 2073GB410200115

Hamburg, 2020-01-15

  
MEDCERT Certification Body  
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

**Appendix of EC Certificate of Conformity**

Process No.: QS – 2073

Certificate No.: 2073GB410200115

**List of locations included in the scope of certificate**

**Robutec AG  
Dornierstrasse 11  
9423 Altenrhein  
Switzerland**

– End of list –

This appendix is integral part of the above-referenced certificate.  
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## Appendix of EC Certificate of Conformity

Process No.: QS – 2073

Certificate No.: 2073GB410200115

### List of products / product categories included in the scope of certificate

#### **Sterile and non-sterile medical devices in the field of ophthalmology**

- **Lens injection systems**
- **Injection systems for the transplantation of corneal tissue**
- **Phaco instruments and accessories**
- **Fluidics cassette systems**

– End of list –

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