

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)

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MEDCERT Identification Number: 0482



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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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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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