

EC-Certificate of Conformity

The Notified Body

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

herewith confirms that the company

Medicel AG
Dornierstrasse 11
9423 Altenrhein
Switzerland

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

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**
- **Tonometer and accessories**

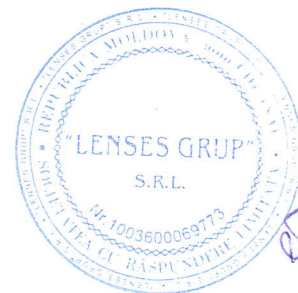
The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 26 July 2020

Report No.: 2073SA17F
Process No.: QS – 2073
Certificate No.: 2073GB410160623



Hamburg, 23 June 2016

MEDCERT Identification No.: 0482

MEDCERT Certification Body
(Rainer Klatt)



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

Certificate

The Certification Body

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

herewith confirms that the company

**Medicel AG
Dornierstrasse 11
9423 Altenrhein
Switzerland**

With its facility as per attachment 1

has introduced, applies and maintains a Quality Management System in the area of:

**Design, manufacture, purchase, packaging and labelling, storage
and distribution of 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**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 26 July 2021

Report No.: 2073FS20F
Process No.: QS – 2073
Certificate No.: 2073GB445181023

Hamburg, 23 October 2018


MEDCERT Certification Body
(Lorenz Runge)



**Attachment 1
Certificate
QS - 2073**

This attachment is valid only in connection with certificate No: 2073GB445181023

Facility

**Robutec AG
Dornierstrasse 11
9423 Altenrhein
Switzerland**

Hamburg, 23 October 2018



MEDCERT Certification Body
(Lorenz Runge)



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00