



# CERTIFICATE



This is to certify that the company

## Medicel AG

Dornierstrasse 11  
9423 Altenrhein  
Switzerland

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

### Scope:

Design, manufacture, storage and distribution of sterile and non-sterile lens injection systems, consisting of disposable lens injector sets, disposable cartridge sets and reusable lens injectors; sterile injectors for the transplantation of corneal transplants; sterile and non-sterile phaco instruments, consisting of disposable and reusable irrigation/aspiration instruments, phaco needles, phaco wrenches, phaco sleeves, phaco tips, trocar blades, trocar cannulas and trocar templates; sterile fluidics systems, consisting of phaco cassettes, drop chambers and tubes

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2003 + Cor. 1 : 2009

Certificate registration no.	494600 MP23CMDR
Certificate unique ID	170653328
Effective date	2016-07-25
Expiry date	2018-12-08
Frankfurt am Main	2016-07-25



DQS Medizinprodukte GmbH is a CMDCAS recognized registrar (Canadian Medical Devices Conformity Assessment System).

## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Maxim Shkolnikov  
Product Manager



**Annex to certificate**  
**Certificate registration No.: 494600 MP23CMDR**  
**Certificate unique ID: 170653328**  
**Effective date: 2016-07-25**



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### **Location**

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**Robutec GmbH**  
Luchten 1262  
9427 Wolfhalden  
Switzerland

Manufacture of sterile and non-sterile lens injection systems consisting of disposable lens injector sets, disposable cartridge sets and reusable lens injectors, sterile injectors for the transplantation of corneal transplants, sterile and non-sterile phaco instruments consisting of disposable and reusable irrigation/aspiration instruments, phaco needles, phaco wrenches, phaco sleeves, phaco tips, trocar blades, trocar cannulas and trocar templates, sterile fluidics systems, consisting of phaco cassettes, drop chambers and tubes

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Dornierstrasse 11  
9423 Altenrhein  
Switzerland

Manufacture of sterile and non-sterile lens injection systems consisting of disposable lens injector sets, disposable cartridge sets and reusable lens injectors, sterile injectors for the transplantation of corneal transplants, sterile and non-sterile phaco instruments consisting of disposable and reusable irrigation/aspiration instruments, phaco needles, phaco wrenches, phaco sleeves, phaco tips, trocar blades, trocar cannulas and trocar templates, sterile fluidics systems, consisting of phaco cassettes, drop chambers and tubes