



# CERTIFICATE



This is to certify that the company

## Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1  
79331 Teningen  
Germany

with the organizational units/sites as listed in the annex

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

Scope of certificate and applicable country-specific requirements:

Design, manufacturing and distribution of surgical devices (bipolar and monopolar instruments, cables, adapters, connectors and handpieces for electrosurgery) and of non-active medical devices (Uterine manipulator)  
Manufacturing and repair of surgical instruments, conventional and CNC-production of machined parts and threads, laser welding, plastic coating for medical devices  
**-CND, JPN, USA (a,b,c,d)**

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 : 2016 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope  
(full references are listed in the annex)

Certificate registration no.	003171 MDSAP16
Certificate unique ID	170704535
Effective date	2018-03-29
Expiry date	2021-03-28
Frankfurt am Main	2018-03-29



### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Szymon Kurdyn  
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)  
**DQS Medizinprodukte GmbH is authorised under the Medical Devices Single Audit Program.**  
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



**Annex to certificate**  
**Certificate registration No.: 003171 MDSAP16**  
**Certificate unique ID: 170704535**  
**Effective date: 2018-03-29**

## **Günter Bissinger Medizintechnik GmbH**

Hans-Theisen-Str. 1  
79331 Teningen  
Germany

### **Location**

### **Scope**

#### **IBISMED Medizintechnik GmbH**

Im Camisch 40  
07768 Kahla  
Germany

Manufacturing and repair of surgical instruments, conventional and CNC-production of machined parts and threads, laser welding, plastic coating for medical devices.  
**-CND, JPN, USA (a,b,c,d)**  
**DUNS No. 331861562**

#### **Günter Bissinger Medizintechnik GmbH**

Hans-Theisen-Str. 1  
79331 Teningen/Baden  
Germany

Design, manufacturing, repair and distribution of surgical devices (RF-surgical unit Compact Coagulator 8070, sterile / non-sterile bipolar and monopolar instruments, and accessories for electrosurgery) and of non-active medical devices (Uterine manipulator, surgical instruments of class I)  
**-CND, JPN, USA (a,b,c,d)**  
**DUNS No. 326515533**



## Annex to certificate

Certificate registration No.: 003171 MDSAP16

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## Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1  
79331 Teningen  
Germany

### Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821