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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

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
Certificate unique ID: 170704535
Effective date: 2018-03-29

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