



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1
79331 Teningen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Non active instruments, RF surgical devices and accessories according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 003171 MR2

Certificate unique ID 170775967

Effective date 2021-05-07

Expiry date 2024-05-26

Frankfurt am Main 2021-05-07

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate

Certificate registration No.: 003171 MR2

Certificate unique ID: 170775967

Effective date: 2021-05-07

Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1
79331 Teningen
Germany

Device family	Device	Class
RF surgical devices and accessories:	RF-surgery device Compact Coagulator 8070	IIb
	Bipolar instruments and accessories for RF-surgery	
	Monopolar instruments and accessories for RF-surgery	
	Monopolar electrodes in sterile and non-sterile version	
Non active instruments:	Bipolar forceps in sterile and non-sterile version	
	Uterine manipulator	IIa
	Trokar	IIa



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:

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)

Manufacturing and repair of surgical instruments, conventional and CNC-production of machined parts and threads, laser welding, plastic coating for medical devices

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:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	003171 MP2016
Certificate unique ID	170770544
Effective date	2021-03-29
Expiry date	2024-03-28
Frankfurt am Main	2021-03-29



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de



Annex to certificate

Certificate registration No.: 003171 MP2016

Certificate unique ID: 170770544

Effective date: 2021-03-29

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.

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)