



# CERTIFICATE



This is to certify that the company

## Biedermann Motech GmbH & Co. KG

Bertha-von-Suttner-Straße 23  
78054 VS-Schwenningen  
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, Production and Sales of Orthopaedic Implants and Instruments  
-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.	003387 MDSAP16
Certificate unique ID	170704006
Effective date	2018-08-24
Expiry date	2021-08-23
Frankfurt am Main	2018-08-24



### DQS Medizinprodukte GmbH

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**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.: 003387 MDSAP16**

**Certificate unique ID: 170704006**

**Effective date: 2018-08-24**

## Biedermann Motech GmbH & Co. KG

Bertha-von-Suttner-Straße 23

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Germany

### Audited site

### DUNS No., site scope and country-specific requirements

#### **Biedermann Motech GmbH & Co. KG**

Bertha-von-Suttner-Straße 23

78054 VS-Schwenningen

Design, Production and Sales of Orthopaedic  
Implants and Instruments

**-USA (a,b,c,d)**

**DUNS No. 320249162**



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### 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