



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 certification:
Design, Production and Sales of Orthopaedic Implants and Instruments
-AUS (a), 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

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	003387 MDSAP16
Certificate unique ID	170771168
Effective date	2020-07-30
Expiry date	2021-08-23
Frankfurt am Main	2020-07-30



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is recognized 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: 170771168

Effective date: 2020-07-30

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Bertha-von-Suttner-Straße 23

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Audited site

Biedermann Motech GmbH & Co. KG

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78054 VS-Schwenningen

Germany

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

Design, Production and Sales of Orthopaedic
Implants and Instruments

-AUS (a), 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