



# CERTIFICATE



This is to certify that the company

## pro med instruments GmbH

Bötzingen Straße 38  
79111 Freiburg  
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, development, manufacturing and distribution of surgical instruments and retractor systems, headrest systems, skull pins, bipolar electrosurgical forceps and cables.

**-AUS (a), BRA, 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.	221096 MDSAP16
Certificate unique ID	170710051
Effective date	2019-02-13
Expiry date	2022-01-27
Frankfurt am Main	2019-02-13



### 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.: 221096 MDSAP16**  
**Certificate unique ID: 170710051**  
**Effective date: 2019-02-13**



## **pro med instruments GmbH**

Bötzingen Straße 38  
79111 Freiburg  
Germany

### **Audited site**

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

**pro med instruments GmbH**  
Bötzingen Straße 38  
79111 Freiburg  
Germany

Design, development, manufacturing and distribution of surgical instruments and retractor systems, headrest systems, skull pins, bipolar electro-surgical forceps and cables; customer service, incoming inspection, storage and shipping.  
**-AUS (a), BRA, CND, JPN, USA (a,b,c,d)**  
**DUNS No.: 313517922**

**pro med instruments GmbH**  
Customer Service  
Waldmatten 6  
79224 Umkirch  
Germany

Customer service, incoming inspection, storage and shipping of surgical instruments and retractor systems, headrest systems, skull pins, bipolar electro-surgical forceps and cables.  
**-AUS (a), BRA, CND, JPN, USA (a,b,c,d)**  
**DUNS No.: 315598763**

**Feinmechanik GmbH**  
Waldmatten 6  
79224 Umkirch  
Germany

Manufacturing and distribution of surgical instruments, retractors systems and headrest systems; customer service, incoming inspection, storage and shipping.  
**-AUS (a), BRA, CND, JPN, USA (a,b,c,d)**  
**DUNS No.: 315598763**



**Annex to certificate**  
**Certificate registration No.: 221096 MDSAP16**  
**Certificate unique ID: 170710051**  
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## **pro med instruments GmbH**

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Germany

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

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
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