



CERTIFICATE



This is to certify that the company

Möller Medical GmbH

Wasserkuppenstr. 29-31
36043 Fulda
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 and development, manufacturing, servicing and distribution of

- pump systems and associated devices (pump, foot switch, auto flow sensor, tube sets)
- coaxial needles
- breast localization needles
- biopsy guns and biopsy needles
- coaxial and fine needles
- bone marrow needles

for neurosurgery, cardiology, aesthetics and blood transfusion and radiology.

-AUS (a), BRA, CND, 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. | 518554 MDSAP16 |
| Certificate unique ID | 170706789 |
| Effective date | 2018-05-19 |
| Expiry date | 2021-05-18 |
| Frankfurt am Main | 2018-05-19 |



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.: 518554 MDSAP16

Certificate unique ID: 170706789

Effective date: 2018-05-19

Möller Medical GmbH

Wasserkuppenstr. 29-31

36043 Fulda

Germany

Audited site

Möller Medical GmbH
Wasserkuppenstr. 29-31
36043 Fulda
Germany

DUNS No., site scope and country-specific requirements

Design and development, manufacturing, servicing and distribution of

- pump systems and associated devices (pump, foot switch, auto flow sensor, tube sets)
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- coaxial and fine needles
- bone marrow needles

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DUNS No. 320405061



Annex to certificate

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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 |