



CERTIFICATE



This is to certify that the company

DOCERAM Medical Ceramics GmbH

Hesslingsweg 65 - 67
44309 Dortmund
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 and distribution of zirconia ceramics for dental restoration and coloring liquids for dental zirconoxide material.

-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.	533551 MDSAP16
Certificate unique ID	170734075
Effective date	2019-02-13
Expiry date	2021-04-19
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.: 533551 MDSAP16
Certificate unique ID: 170734075
Effective date: 2019-02-13



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Audited site

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Hesslingsweg 65 - 67
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DUNS No., site scope and country-specific requirements

Design and development, manufacturing and distribution of dental products (coloring liquids), dental products and restoration materials for dental, pontines and caps, zirconia ceramics for dental restoration and coloring liquids for dental zirconoxide material.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
DUNS No.: 537713567



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Full references of country-specific requirements of AA 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