



CERTIFICATE



This is to certify that the company

Cendres+Métaux SA

Rue de Boujean 122
CH-2501 Biel/Bienne
Switzerland

has implemented and maintains a **Quality Management System**.

Scope of certificate and applicable country-specific requirements:

Design, development and manufacturing of Root Canal Drills and Reamers, Wires and Tubes, Posts, Wires for Clasps and Posts, High-Performance Polymer for Dental Prosthesis, gold based alloys and precious metal alloys for clinical use such as Dental Casting Alloys (included for bonding alloys): High Gold Bonding Alloys, Medium Gold Bonding Alloys, Palladium Based Bonding Alloys, High Gold Casting Alloys, Medium Gold Casting Alloys, Silver-Palladium Casting Alloys and Universal Alloys, Non-Precious Alloys, Wires for Laser Welding, Root Canal Posts and Anchors, Dental Solders, Dental Prosthesis Attachments: Slide Attachments, Anchors, Bars, Screws and Retention Elements, Service Sets and Auxiliary, Dental Implant Suprastructure, permanent dental implant suprastructure including endosseous dental implant abutments, dental ceramic, dental composite.

-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.	403633 MDSAP16
Certificate unique ID	170723885
Effective date	2019-01-24
Expiry date	2022-01-23
Frankfurt am Main	2019-01-24



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.: 403633 MDSAP16
Certificate unique ID: 170723885
Effective date: 2019-01-24



Cendres+Métaux SA

Rue de Boujean 122
CH-2501 Biel/Bienne
Switzerland

Audited site

Cendres+Métaux SA
Rue de Boujean 122
CH-2501 Biel/Bienne
Switzerland

DUNS No., site scope and country-specific requirements

Design, development and manufacturing of Root Canal Drills and Reamers, Wires and Tubes, Posts, Wires for Clasps and Posts, High-Performance Polymer for Dental Prosthesis, gold based alloys and precious metal alloys for clinical use such as Dental Casting Alloys (included for bonding alloys): High Gold Bonding Alloys, Medium Gold Bonding Alloys, Palladium Based Bonding Alloys, High Gold Casting Alloys, Medium Gold Casting Alloys, Silver-Palladium Casting Alloys and Universal Alloys, Non-Precious Alloys, Wires for Laser Welding, Root Canal Posts and Anchors, Dental Solders, Dental Prosthesis Attachments: Slide Attachments, Anchors, Bars, Screws and Retention Elements, Service Sets and Auxiliary, Dental Implant Suprastructure, permanent dental implant suprastructure including endosseous dental implant abutments, dental ceramic, dental composite.

-CND, JPN, USA (a,b,c,d)

DUNS No.: 487506230



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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