CERTIFICATE

This is to certify that the company

Cendres+Métaux SA

Rue de Boujean 122
2501 Biel/Bienne
Switzerland

with the organizational units/sites as listed in the annex

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

Scope of certification:
Design, development, manufacturing and Distribution of
- Dental Implant components (Anchor abutments on implants)
- Dental Attachments (Slide attachments, Anchors, Bars, Screws and retention elements and Auxiliary parts/instruments)
- Endodontics products (Root canal posts, Root canal anchors and Auxiliary parts/instruments)
- Dental Ceramics
- High-Performance Polymer for dental prosthesis
- Precious metal dental alloys (Ceramic alloy, Casting alloys, Universal alloy, Solders, Laser welding and Round wires)

-AUS (a), 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

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

Certificate registration no.	548505 MDSAP16
Certificate unique ID	1000119870
Effective date	2023-12-22
Expiry date	2026-12-21
Frankfurt am Main	2023-12-22

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

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Tel. +49 (0) 69 95427-300, info-med@dqs.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
The validity of this certificate can only be verified by the QR-code.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 548505 MDSAP16
Certificate unique ID: 1000119870
Effective date: 2023-12-22

Cendres+Métaux SA

Rue de Boujean 122
2501 Biel/Bienne
Switzerland

Audited site	REPs FEI No.: site scope and country-specific requirements
548505 **Cendres+Métaux SA** Rue de Boujean 122 2501 Biel/Bienne Switzerland	Design, development, manufacturing and Distribution of ▪ Dental Implant components (Anchor abutments on implants) ▪ Dental Attachments (Slide attachments, Anchors, Bars, Screws and retention elements and Auxiliary parts/instruments) ▪ Endodontics products (Root canal posts, Root canal anchors and Auxiliary parts/instruments) ▪ Dental Ceramics ▪ High-Performance Polymer for dental prosthesis ▪ Precious metal dental alloys (Ceramic alloy, Casting alloys, Universal alloy, Solders, Laser welding and Round wires) **-AUS (a), CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F002480**

Annex to certificate
Certificate registration No.: 548505 MDSAP16
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Rue de Boujean 122
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Switzerland

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. 665/2022 RDC ANVISA n. 551/2021 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