

Wir, die Firma

Nous, la maison

We, the company

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

erklären hiermit in alleiniger
Verantwortung, dass die folgen-
den Produkte

déclarons sous notre seule
responsabilité que les produits
suivants

declare under our sole responsi-
bility that the following products

Service-Set

gemäss beiliegender Liste

Service-Set

selon liste annexée
List of CM- Service-Set V2

Service-Set

according to attached list

konform sind zu den folgenden
normativen Dokumenten:

sont conformes aux documents
normatifs suivants:

are in conformity with the
following normative documents:

Grundlegende Anforderungen

gemäss Anhang I, 93/42/EWG,
2007/47/EG

Exigences essentielles

selon l'annexe I, 93/42/CEE,
2007/47/CE

Essential Requirements

according to annex I, 93/42/EEC,
2007/47/EC

Normen: vgl. beiliegende Liste

Normes: cf. liste annexée

Standards: see attached list

List of laws, standards and norms Product Group Service-Set Edition 5

Klassifizierung gemäss
Anhang IX, 93/42/EWG:
vergl. beiliegende Liste

Classification selon
l'annexe IX, 93/42/CEE:
Cf. liste annexée des produits
List of CM- Service-Set V2

Classification according to
annex IX, 93/42/EEC:
see attached list of products

**Konformitätsbewertungs-
verfahren:**

93/42/EWG

Klasse I: Anhang VII

Übrige Klassen: Anhang II
(ohne Abschnitt 4)

**Procédure d'évaluation de la
conformité:**

93/42/CEE

Classe I: Annexe VII

Autres classes: Annexe II
(sans section 4)

**Conformity assessment
procedure:**

93/42/EEC

Class I: Annex VII

All other classes: Annex II
(Without section 4)

Benannte Stelle:

Klasse I: Benannte Stelle nicht
erforderlich.

Übrige Klassen: SQS (CE 1250)

Organisme notifié:

Classe I: Pas d'organisme notifié
nécessaire.

Autres classes: SQS (CE 1250)

Notified Body:

Class I: No notified body needed.

All other classes: SQS (CE 1250)

Gültigkeit

Validité

2022-04-01

Validity

Diese Konformitätserklärung wird
mit den folgenden Unterschriften
beglaubigt:

Cette déclaration de conformité
est certifiée par les signatures
suivantes:

This declaration is certified by
the following signatures:

Biel/Bienne, **2019-03-28**



Andrea Sparti
Regulatory Affairs Manager



Remi Meier
Head of Quality Management
Product Safety Officer

List of CM-service-sets

Part_class I_R6: Conformity assesement: MDD 93/42/CEE appendix VII

Version V2

#	product group	product	article	article-number	class	rule according anexe	specific standerds	general standards	delay
1	Service-Sets	Service Set Dalbo®-Kugelanker	Gewindebohrhalter	070213	class I	6	none	see: Standards list (current)	31.12.2018
2	Service-Sets	Service Gerber RZ	Steckschlüssel	070262	class I	6	none	see: Standards list (current)	31.12.2018
3	Service-Sets	Service Set Dalbo®-Kugelanker	Steckschlüssel	070498	class I	6	none	see: Standards list (current)	31.12.2018
4	Service-Sets	Service Set Umbau Patrizie in Dalbo®-Verankerung	Steckschlüssel	070547	class I	6	none	see: Standards list (current)	31.12.2018
5	Service-Sets	Service Set Umbau-Verankerung	Steckschlüssel	070547	class I	6	none	see: Standards list (current)	31.12.2018

Part_class IIa_R6: Conformity assesement: MDD 93/42/CEE appendix II.3, Notified Body: SQS (CE 1250)

Version V2

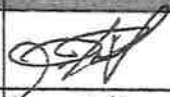


#	product group	product	article	article-number	class	rule according anexe	specific standerds	general standards	delay
1	Service-Sets	Service Set Dalbo®-Kugelanker	Gewindebohrer M 1.4	070211	class IIa	6	none	see: Standards list (current)	31.12.2018
2	Service-Sets	Service Set Umbau-Verankerung	Schneideisen MF 1.40 x 0.20	070365	class IIa	6	none	see: Standards list (current)	31.12.2018
3	Service-Sets	Service Gerber RZ	Schneideisen MF 1.20 x 0.20	070458	class IIa	6	none	see: Standards list (current)	31.12.2018
4	Service-Sets	Service Set Dalbo®-Kugelanker	Senkfräse	070499	class IIa	6	ISO 1797	see: Standards list (current)	31.12.2018
5	Service-Sets	Service Set Dalbo®-Kugelanker	Bohrer 1.15 mm WS.	072429	class IIa	6	none	see: Standards list (current)	31.12.2018
6	Service-Sets	Service Set Umbau-Verankerung	Hohlstimfräse	072494	class IIa	6	none	see: Standards list (current)	31.12.2018
7	Service-Sets	Service Set Umbau-Verankerung	Hohlstimfräse zum Vorfräsen	072590	class IIa	6	none	see: Standards list (current)	31.12.2018
8	Service-Sets	Service Set Dalbo®-Kugelanker	Zentrierbohrer 1.0 mm WS	080798	class IIa	6	none	see: Standards list (current)	31.12.2018

Part_class IIa_R8: Conformity assesement: MDD 93/42/CEE appendix II.3, Notified Body: SQS (CE 1250)

Version V2

#	product group	product	article	article-number	class	rule according anexe	specific standerds	general standards	delay
1	Service-Sets	Service Set Umbau Patrizie in Dalbo®-Verankerung	Matrizie Dalbo-Verankerung	051511	class IIa	8	none	see: Standards list (current)	31.12.2018
2	Service-Sets	Service Gerber RZ	Reparaturkern	051666	class IIa	8	none	see: Standards list (current)	31.12.2018
3	Service-Sets	Service Set Umbau Patrizie in Dalbo®-Verankerung	Umbau-Patrizie mit Innengewinde	052089	class IIa	8	none	see: Standards list (current)	31.12.2018
4	Service-Sets	Service Set Umbau-Verankerung	Umbau-Patrizie mit Innengewinde	052089	class IIa	8	none	see: Standards list (current)	31.12.2018
5	Service-Sets	Service Set Dalbo®-Kugelanker	Patrizie mit Gewindezapfen	052091	class IIa	8	none	see: Standards list (current)	31.12.2018
6	Service-Sets	Service Set Dalbo®-Kugelanker	Service Set Dalbo® -Kugelanker	054744	class IIa	8	none	see: Standards list (current)	31.12.2018
7	Service-Sets	Service Set Umbau Patrizie in Dalbo®-Verankerung	Service Set Umbau-Patrizie Dalbo® -Verankerung	054758	class IIa	8	none	see: Standards list (current)	31.12.2018
8	Service-Sets	Service Gerber RZ	Service Set Gerber RZ	054892	class IIa	8	none	see: Standards list (current)	31.12.2018
9	Service-Sets	Service Set Umbau-Verankerung	Service Set Umbau-Verankerung	055391	class IIa	8	none	see: Standards list (current)	31.12.2018
10	Service-Sets	Service Set Dalbo®-Kugelanker	Matrizie Dalbo®-Classic elliptic E	055887	class IIa	8	none	see: Standards list (current)	31.12.2018
11	Service-Sets	Service Set Umbau-Verankerung	Matrizie Dalbo®-Classic elliptic	055887	class IIa	8	none	see: Standards list (current)	31.12.2018

List of CM-service-sets

First Name / Name	Function	Date	Signature
Mathias Föh	Product Manager	20.4.2016	
Dr. Niklaus Baltzer	Product Safety Officer	20.04.2016	
Remi Meier	Head of Quality Management	20.4.2016.	

Change Control:

Version	Date	Description of the Change	Reason of the Change
Version 2	01.02.2016	Integration of all spare parts in the lists (no spare part articles on the list of Service-sets)	spare parts are in all points of view equivalent to the rest of articles
Version 2	11.02.2016	Integration of all products on demand in this list (no articles)	products on demand are in all points of view equal to the rest of articles

Valid for the project and/or the product(s): product group service-sets (KE5)

1. Laws for medical devices

The actual laws for medical devices are on CL 4.101 ("Gesetzessammlung Teil 2")

2. Standards and norms for medical devices

Based on SNV Service

No	Code	No	Title	Issue date	Valid
1	SN EN ISO	9001	Quality management systems – Requirements	2015-09	<input type="checkbox"/>
2	SN EN ISO	14001	Environmental Management System	2015-09	<input type="checkbox"/>
3	SN EN ISO	13485	Medical devices, Quality management systems, Requirements for Regulatory purposes	2016-03	<input checked="" type="checkbox"/>
4	SN EN ISO	14971	Medical devices - Application of risk management to medical devices	2012-09	<input checked="" type="checkbox"/>
5	SN EN ISO	15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2017-02	<input checked="" type="checkbox"/>
6	SN EN	1041+A1	Information supplied by the manufacturer of medical devices	2013-10	<input checked="" type="checkbox"/>
7	SN EN ISO/IEC	17050-1	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements	2010-08	<input checked="" type="checkbox"/>
8	SN EN ISO/IEC	17050-2	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation	2004-11	<input checked="" type="checkbox"/>
9	IEC	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015-02	<input checked="" type="checkbox"/>
			Technical Corrigendum	2016-07	
	SN EN	62366+A1	Medical devices - Part 1: Application of usability engineering to medical devices	2016-05	
10	SN EN ISO	17664	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable devices	2018-04	<input checked="" type="checkbox"/>
11	SN EN	1639	Dentistry - Medical devices for dentistry - Instruments	2010-03	<input type="checkbox"/>
12	SN EN	1640	Dentistry - Medical devices for dentistry - Equipment	2010-03	<input type="checkbox"/>
13	SN EN	1641	Dentistry - Medical devices for dentistry - Materials	2010-03	<input type="checkbox"/>
14	SN EN ISO	12836	Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy	2015-12	<input type="checkbox"/>
15	SN EN	10204	Metallic products - Types of inspection documents	2004-12	<input type="checkbox"/>
16	ISO	22674	Dentistry - Metallic materials for fixed and removable restorations and appliances	2016-01	<input checked="" type="checkbox"/>
17	SN EN ISO	4049	Dentistry -- Polymer-based restorative materials	2010-03	<input type="checkbox"/>
18	SN EN ISO	10477	Dentistry -- Polymer-based crown and bridge materials	2005-03	<input type="checkbox"/>
19	ISO	9693-1	Dentistry - Compatibility testing - Part 1: Metal-ceramic systems	2012-02	<input type="checkbox"/>
20	SN EN ISO	9333	Dentistry – Brazing materials	2006-10	<input type="checkbox"/>
21	SN EN ISO	28319	Dentistry - Laser welding	2010-08	<input type="checkbox"/>

No	Code	No	Title	Issue date	Valid
22	ASTM	F 67	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700) Titan Grad 1(1083)/2 KV(780)/3(720)/4(721)/4 KV(725)/4 KV Dolder(1082)/4 CP4 low iron(1273)/4B ISO 5832-2(977)/Hannibal(976)	2013	<input type="checkbox"/>
23	ISO	5832-2	Implants for surgery - Metallic materials - Part 2: Unalloyed titanium Titan Grad 2(556)/2 KV(780)/3(720)/4(721)	2018-03	<input type="checkbox"/>
24	ASTM	F 136	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) Syntax(555)/TiAl6V4 ELI(555)/Titan64(555)/Titan Grade 5(555)/Grade 23(555)/Certain(995)	2013	<input type="checkbox"/>
25	ASTM	B 348	Standard Specification for Titanium and Titanium Alloy Bars and Billets Titan Grade 36/Ti45Nb (1228)	2013	<input type="checkbox"/>
26	ASTM	F 899-12b	Standard Specification for Wrought Stainless Steels for Surgical Instruments	2012	<input checked="" type="checkbox"/>
27	ASTM	F2820	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	2012	<input type="checkbox"/>
28	SN EN ISO	7153-1	Surgical instruments - Materials - Part 1: Metals	2016-12	<input type="checkbox"/>
29	SN EN	10088-3	Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes 1.4435 (stainless steel: Medstahl, Chr Spezial 35)(1028)	2014-12	<input checked="" type="checkbox"/>
30	ASTM	F75	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	2012	<input type="checkbox"/>
31	ASTM	F799	Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	2011	<input type="checkbox"/>
32	ASTM	F1537	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	2011	<input type="checkbox"/>
33	ISO	5832-4	Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy	2014-09	<input type="checkbox"/>
34	ISO	5832-12	Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy	2007-05	<input type="checkbox"/>
35	ISO	13356	Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	2015-09	<input type="checkbox"/>
36	SN EN ISO	18064	Thermoplastic elastomers - Nomenclature and abbreviated terms	2015-02	<input type="checkbox"/>
37	SN EN ISO	1797-1	Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals	2017-09	<input checked="" type="checkbox"/>
38	SN EN ISO	6872	Dentistry - Ceramic materials	2015-09	<input type="checkbox"/>
39	ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2016-10	<input type="checkbox"/>

3. Standards and norms for testing medical devices

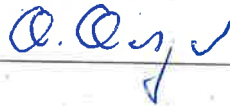
No	Code	No	Title	Issue date	Valid
1	ASTM	D 638	Standard Test Method for Tensile Properties of Plastics	2014	<input type="checkbox"/>
2	ASTM	D 790-17	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	2017	<input type="checkbox"/>
3	ASTM	B 265-15	Standard Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate	2015	<input type="checkbox"/>
4	DIN	51004	Thermal analysis; determination of melting temperatures of crystalline materials by differential thermal analysis	1994-06	<input type="checkbox"/>
5	DIN	51045-1	Determination of the thermal expansion of solids - Part 1: Basic rules (WAK)	2005-08	<input type="checkbox"/>
6	ISO	6892-1	Metallic materials - Tensile testing - Part 1: Method of test at room temperature	2016-06	<input type="checkbox"/>
7	ISO	10271	Dentistry - Corrosion test methods for metallic materials (edition 2)	2011-08	<input type="checkbox"/>
8	ISO	6507-1	Metallic materials - Vickers hardness test - Part 1: Test method (ISO 6507-1:2005)	2018-01	<input type="checkbox"/>
9	ISO	7405	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry AMD 1: Positive control material	2008-12 2013-07	<input checked="" type="checkbox"/>
10	ISO	7491	Dental materials -- Determination of colour stability	2000-09	<input type="checkbox"/>
11	SN EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing AC	2010-03 2010-09	<input checked="" type="checkbox"/>
12	SN EN ISO	10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014-12	<input type="checkbox"/>
13	SN EN ISO	10993-5	Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity	2009-11	<input checked="" type="checkbox"/>
14	SN EN ISO	10993-6	Biological evaluation of medical devices. Tests for local effects after implantation	2017-05	<input type="checkbox"/>
15	SN EN ISO	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2013-12	<input checked="" type="checkbox"/>
16	SN EN ISO	10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2009-08	<input type="checkbox"/>
17	SN EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012-09	<input type="checkbox"/>
18	SN EN ISO	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2009-08	<input type="checkbox"/>
19	SN EN ISO	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2009-11	<input type="checkbox"/>
20	SN EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009-08	<input type="checkbox"/>
21	ISO	14801	Dentistry - Implants - Dynamic loading test for endosseous dental implants	2016-11	<input type="checkbox"/>
22	SN EN ISO	20795-1	Dentistry - Base polymers, Part 1: Denture base polymers	2013-05	<input type="checkbox"/>
23	SN EN ISO	20795-2	Dentistry - Base polymers - Part 2: Orthodontic base polymers	2013-05	<input type="checkbox"/>

Validity for the project and/or the product is confirmed by x

Approval


Alain Denzer
Clinical Affairs Manager

Datum: 2019-03-25

Visum: 

Remi Meier
Head of Quality Management

Datum: 2019-03-25

Visum: 

4. Änderungskontrolle

Ist eine Schulung erforderlich, hat der Prozesseigner die betroffenen Personen zu Schulen. Die Schulung ist mittels FO 6.301 „Nachweis interne Schulung“ zu dokumentieren. Der Nachweis ist QMA zur Archivierung abzugeben.

Die Schulungen sind rasch möglichst durchzuführen da sonst die Änderung nicht durchgesetzt werden kann.

5. Änderungsprotokoll

Änderungs-Datum	Seite	Pos./ Punkt	Beschreibung der Änderung	Begründung der Änderung.	Antragsteller	Schulung notwendig ¹⁾ Schulung nicht notwendig ²⁾
13.10.2017	alle	Alle	Neugestaltung des Formulars im Excel für einfachere Verwaltung und Sortierung	Neugestaltung des Formulars im Excel für einfachere Verwaltung und Sortierung Änderung ohne Schulungsbedarf, da Anwender an der Verbesserung beteiligt waren	ble	<input type="checkbox"/> <input checked="" type="checkbox"/>
13.10.2017	Alle	alle	Einfügen der neuen Versionen von: - ISO 22674:2016-01 - ISO 1797-1:2017-05 - SN EN ISO 10993-6:2017-05 - ISO 14801:2016-11	Generelle Aktualisierung ohne Schulungsbedarf	ble	<input type="checkbox"/> <input checked="" type="checkbox"/>
13.10.2018	N/A	N/A	Versionsänderung von 03 auf 04 wurde nicht dokumentiert	N/A	N/A	<input type="checkbox"/> <input checked="" type="checkbox"/>
13.12.2018	alle	alle	Normenaktualisierung Layoutwechsel auf Word	Generelle Aktualisierung ohne Schulungsbedarf	jka	<input type="checkbox"/> <input checked="" type="checkbox"/>

¹⁾ Datum der durchgeführten Schulung:

²⁾ Falls keine Schulung notwendig ist, bitte im Änderungsprotokoll begründen.