CENDRES+ MÉTAUX Medtech

CE-Konformitätserklärung
CE-Déclaration de Conformité
EC-Declaration of Conformity

FO 00001956 Ausgabe 04

Erstellt: MQMA/rme Visum:
Geprüft: MQMA/jka Visum
Freigabe MERA/asp Visum:
Ausgabe-Datum: 25.03.2019

Wir, die Firma	Nous, la maison **Cendres+Métaux SA** **Rue de Boujean 122** **CH-2501 Biel/Bienne**	We, the company
erklären hiermit in alleiniger Verantwortung, dass die folgenden Produkte	déclarons sous notre seule responsabilité que les produits suivants	declare under our sole responsibility that the following products
Hochleistungspolymere für Zahnersatz	**Polymère à hautes performances pour restaurations dentaires**	**High-performance Polymer for dental Prosthetics**
gemäss beiliegender Liste	selon liste annexée **List of PEKKTON Products V1**	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 List of laws, standards and norms Product Group PEKKTON Edition 05	**Standards:** see attached list
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 PEKKTON Products V1**	**Classification** according to annex IX, 93/42/EEC: see attached list of products
Konformitätsbewertungsverfahren: 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 Pekkton Products

Part_no medical device

Version: V1

#	product group	product	article	article-number	class	rule according anexe	specific standerds	general standards	delay
1	PEKKTON	Pekkton® ivory	Press-Stempel mit Dichtung	08000141	no medical device		none	see: Standards list (current)	31.12.2018
2	PEKKTON	Pekkton® ivory	Press-Stem. Packung zu 3 Stück	08000517	no medical device		none	see: Standards list (current)	31.12.2018
3	PEKKTON	Pekkton® ivory	Einweg Press-Stempel Ø12 mm	06000626	no medical device		none	see: Standards list (current)	31.12.2018
4	PEKKTON	Pekkton® ivory	Einweg Press-Stempel Ø26 mm	08000627	no medical device		none	see: Standards list (current)	31.12.2018
5	PEKKTON	Pekkton® ivory	PEKKpress Muffel-Set 200g	08000628	no medical device		none	see: Standards list (current)	31.12.2018
6	PEKKTON	Pekkton® ivory	PEKKpress Muffel-Set 600g	08000629	no medical device		none	see: Standards list (current)	31.12.2018

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

Version: V1

#	product group	product	article	article-number	class	rule according anexe	specific standerds	general standards	delay
1	PEKKTON	Pekkton® ivory	Pekkton ivory Press-Rohling	01060003	class IIa	8	none	see: Standards list (current)	31.12.2018
5	PEKKTON	Pekkton® ivory	Pekkton®ivory Millingblank98.5/t16mm	01060011	class IIa	8	none	see: Standards list (current)	31.12.2018
6	PEKKTON	Pekkton® ivory	Pekkton®ivory Millingblank98.5/t20mm	01060020	class IIa	8	none	see: Standards list (current)	31.12.2018
7	PEKKTON	Pekkton® ivory	Pekkton®ivory Millingblank98.5/t24mm	01060022	class IIa	8	none	see: Standards list (current)	31.12.2018
8	PEKKTON	Pekkton® ivory	Pekkton®ivory Millingblank95/t16mm	01060028	class IIa	8	none	see: Standards list (current)	31.12.2018
9	PEKKTON	Pekkton® ivory	Pekkton®ivory Millingblank95/t20mm	01060030	class IIa	8	none	see: Standards list (current)	31.12.2018
10	PEKKTON	Pekkton® ivory	Pekkton®ivory Millingblank95/t24mm	01060032	class IIa	8	none	see: Standards list (current)	31.12.2018

First Name / Name	Function	Date	Signature
Markus Blumli	Product Manager	26.4.2016	
Remy Meier	Product Safety Officer	26.4.2016.	
Thierry Coppennex	Director of Development	26.4.2016	

Change Control:

Version	Date	Description of the Change	Reason of the Change

Valid for the project and/or the product(s): Product Group Pekkton ivory (HLP01)

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	☐
2	SN EN ISO	14001	Environmental Management System	2015-09	☐
3	SN EN ISO	13485	Medical devices, Quality management systems, Requirements for Regulatory purposes	2016-03	☒
4	SN EN ISO	14971	Medical devices - Application of risk management to medical devices	2012-09	☒
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	☒
6	SN EN	1041+A1	Information supplied by the manufacturer of medical devices	2013-10	☒
7	SN EN ISO/IEC	17050-1	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements	2010-08	☒
8	SN EN ISO/IEC	17050-2	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation	2004-11	☒
9	IEC	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015-02	☒
			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	☐
11	SN EN	1639	Dentistry - Medical devices for dentistry - Instruments	2010-03	☐
12	SN EN	1640	Dentistry - Medical devices for dentistry - Equipment	2010-03	☐
13	SN EN	1641	Dentistry - Medical devices for dentistry - Materials	2010-03	☐
14	SN EN ISO	12836	Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy	2015-12	☐
15	SN EN	10204	Metallic products - Types of inspection documents	2004-12	☐
16	ISO	22674	Dentistry - Metallic materials for fixed and removable restorations and appliances	2016-01	☐
17	SN EN ISO	4049	Dentistry -- Polymer-based restorative materials	2010-03	☒
18	SN EN ISO	10477	Dentistry -- Polymer-based crown and bridge materials	2005-03	☒
19	ISO	9693-1	Dentistry - Compatibility testing - Part 1: Metal-ceramic systems	2012-02	☐
20	SN EN ISO	9333	Dentistry – Brazing materials	2006-10	☐
21	SN EN ISO	28319	Dentistry - Laser welding	2010-08	☐

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	☐
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	☐
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	☐
25	ASTM	B 348	Standard Specification for Titanium and Titanium Alloy Bars and Billets Titan Grade 36/Ti45Nb (1228)	2013	☐
26	ASTM	F 899-12b	Standard Specification for Wrought Stainless Steels for Surgical Instruments	2012	☐
27	ASTM	F2820	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	2012	☒
28	SN EN ISO	7153-1	Surgical instruments - Materials - Part 1: Metals	2016-12	☐
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	☐
30	ASTM	F75	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	2012	☐
31	ASTM	F799	Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	2011	☐
32	ASTM	F1537	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	2011	☐
33	ISO	5832-4	Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy	2014-09	☐
34	ISO	5832-12	Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy	2007-05	☐
35	ISO	13356	Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	2015-09	☐
36	SN EN ISO	18064	Thermoplastic elastomers - Nomenclature and abbreviated terms	2015-02	☐
37	SN EN ISO	1797-1	Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals	2017-09	☐
38	SN EN ISO	6872	Dentistry - Ceramic materials	2015-09	☐
39	ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2016-10	☐

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	☒
2	ASTM	D 790-17	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	2017	☒
3	ASTM	B 265-15	Standard Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate	2015	☐
4	DIN	51004	Thermal analysis; determination of melting temperatures of crystalline materials by differential thermal analysis	1994-06	☒
5	DIN	51045-1	Determination of the thermal expansion of solids - Part 1: Basic rules (WAK)	2005-08	☐
6	ISO	6892-1	Metallic materials - Tensile testing - Part 1: Method of test at room temperature	2016-06	☐
7	ISO	10271	Dentistry - Corrosion test methods for metallic materials (edition 2)	2011-08	☐
8	ISO	6507-1	Metallic materials - Vickers hardness test - Part 1: Test method (ISO 6507-1:2005)	2018-01	☐
9	ISO	7405	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry AMD 1: Positive control material	2008-12 2013-07	☒
10	ISO	7491	Dental materials -- Determination of colour stability	2000-09	☒
11	SN EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing AC	2010-03 2010-09	☒
12	SN EN ISO	10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014-12	☒
13	SN EN ISO	10993-5	Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity	2009-11	☒
14	SN EN ISO	10993-6	Biological evaluation of medical devices. Tests for local effects after implantation	2017-05	☒
15	SN EN ISO	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2013-12	☒
16	SN EN ISO	10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2009-08	☒
17	SN EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012-09	☒
18	SN EN ISO	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2009-08	☐
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	☐
20	SN EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009-08	☒
21	ISO	14801	Dentistry - Implants - Dynamic loading test for endosseous dental implants	2016-11	☒
22	SN EN ISO	20795-1	Dentistry - Base polymers, Part 1: Denture base polymers	2013-05	☒
23	SN EN ISO	20795-2	Dentistry - Base polymers - Part 2: Orthodontic base polymers	2013-05	☒

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

Approval

Manuel Stebinger
Development Engineer

Datum: 20.02.2019 Visum: M. Steb

Remi Meier
Head of Quality Management

Datum: 22.02.2019. 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	☐☒
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	☐☒
13.10.2018	N/A	N/A	Versionsänderung von 03 auf 04 wurde nicht dokumentiert	N/A	N/A	☐☒
13.12.2018	alle	alle	Normenaktualisierung Layoutwechsel auf Word	Generelle Aktualisierung ohne Schulungsbedarf	jka	☐☒

[1] Datum der durchgeführten Schulung:

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