

## Circular Informativa

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N.º 048/CD/550.20.001

Data: 19/05/2023

Assunto: **Recolha de dispositivos médicos do fabricante Dérig Indústria e Comércio de Materiais Médico-Odontológicos LTDA. EPP com marcação CE indevida**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373;  
E-mail: [cimi@infarmed.pt](mailto:cimi@infarmed.pt); Linha do Medicamento: 800 222 444

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No âmbito de uma ação de fiscalização, realizada pelo INFARMED, I.P., dirigida aos dispositivos médicos do fabricante Dérig Indústria e Comércio de Materiais Médico-Odontológicos LTDA. EPP, foi identificada a disponibilização no mercado de alguns dispositivos médicos que não se encontravam em conformidade com a legislação europeia aplicável, apresentando marcação CE indevida, em virtude de não terem sido sujeitos ao respetivo procedimento de avaliação da conformidade por parte de um organismo notificado, nomeadamente:

1. Os dispositivos médicos que ostentem marcação CE 0120 e cuja data de fabrico seja posterior a 01 de janeiro de 2015, e
2. Os dispositivos médicos que ostentem marcação CE 2460 que não estejam incluídos no âmbito do certificado de conformidade 250861-2017-CE-BRA-NA-PS (incluindo os seus respetivos apêndices) emitido pelo organismo notificado DNV Product Assurance AS, em anexo.

Neste sentido, o INFARMED, I.P., em cumprimento do princípio da precaução e zelo pela saúde pública e do princípio da legalidade, ordena a imediata suspensão da comercialização e recolha do mercado dos dispositivos médicos identificados em 1. e 2..

Nesta sequência, o importador, distribuidor e atual mandatário, a entidade Exaktus - Material de Reabilitação Oral Lda, procederá à recolha dos dispositivos médicos afetados.

Assim, as entidades que disponham de unidades dos dispositivos médicos em causa não as podem dispensar ou utilizar, devendo proceder à sua devolução. Para obter informações adicionais, contactar a entidade Exaktus - Material de Reabilitação Oral Lda.

Adicionalmente, no âmbito da cooperação administrativa entre autoridades competentes congéneres e organismos notificados, O INFARMED, I.P. teve conhecimento de que o certificado de conformidade acima identificado foi suspenso no dia 08/05/2023, não tendo sido neste âmbito identificada nenhuma questão de segurança relativa aos dispositivos.

Assim, e não obstante o facto de o mandatário, importador e distribuidor dos dispositivos em apreço, ter declarado não ter disponibilizado no mercado nenhuma unidade de dispositivos médicos do fabricante Dérig Indústria e Comércio de Materiais Médico-Odontológicos LTDA. EPP com data de fabrico posterior a 08/05/2023, o INFARMED, I.P., em cumprimento do princípio da precaução e zelo pela saúde pública e do princípio da legalidade, ordena a suspensão da comercialização dos referidos dispositivos médicos.

A Vogal do Conselho Diretivo

## ANEXO

Certificado de conformidade 250861-2017-CE-BRA-NA-PS (incluindo os seus respetivos apêndices) emitido pelo organismo notificado DNV Product Assurance AS (2460)



## EC Certificate Full Quality Assurance System

Certificate No.:  
250861-2017-CE-BRA-NA-PS Rev. 0.0

Project No.:  
PRJC-552950-2016-MSL-BRA

Valid Until:  
15 November 2023

This is to certify that the quality system of:

### DÉRIG INDÚSTRIA E COMÉRCIO DE MATERIAIS MÉDICO- ODONTOLÓGICOS LTDA. EPP

Rua Lapa, 479 – Chácaras Marco  
06419-020  
Barueri/SP - Brazil

For design, production and final product inspection/testing of:

### Dental Implants

Has been assessed with respect to:

### The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:  
Høvik, 16 November 2018



For:  
DNV GL PRESAFE AS

  
Tone Kolpus

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

DNV GL PRESAFE AS - Vestvassveien 5, N-1583 Høvik, Norway - Registered Enterprise No. NO 887 087 401 MVA

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## EC Certificate Full Quality Assurance System

Certificate No.:  
250861-2017-CE-BRA-NA-PS Rev. 0.0

Project No.:  
PRJC-552950-2016-MSL-BRA

Valid Until:  
15 November 2023

### Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

### Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2018-11-16

### Products covered by this Certificate:

Product Description	Product Name	Class
Implant	Cylindrical Biodent HEX NP 3.3 x 8.5mm	IIb
	Cylindrical Biodent HEX NP 3.3 x 10mm	
	Cylindrical Biodent HEX NP 3.3 x 11.5mm	
	Cylindrical Biodent HEX NP 3.3 x 13mm	
	Cylindrical Biodent HEX NP 3.3 x 15mm	
	Cylindrical Biodent HEX RP 3.75 x 8.5mm	
	Cylindrical Biodent HEX RP 3.75 x 10mm	
	Cylindrical Biodent HEX RP 3.75 x 11.5mm	
	Cylindrical Biodent HEX RP 3.75 x 13mm	
	Cylindrical Biodent HEX RP 3.75 x 15mm	
	Cylindrical Biodent HEX RP 4.0 x 8.5mm	
	Cylindrical Biodent HEX RP 4.0 x 10mm	
	Cylindrical Biodent HEX RP 4.0 x 11.5mm	
	Cylindrical Biodent HEX RP 4.0 x 13mm	
	Cylindrical Biodent HEX RP 4.0 x 15mm	
	Cylindrical Biodent HEX RP 4.0 x 17mm	
	Cylindrical Biodent HEX UP 5.0 x 8.5mm	
	Cylindrical Biodent HEX UP 5.0 x 10mm	
	Cylindrical Biodent HEX UP 5.0 x 11.5mm	
	Cylindrical Biodent HEX UP 5.0 x 13mm	
	Cylindrical Biodent HEX UP 5.0 x 15mm	
Tapered Bioneck TRI NP 3.5 x 8mm		
Tapered Bioneck TRI NP 3.5 x 10mm		
Tapered Bioneck TRI NP 3.5 x 11.5mm		



## EC Certificate Full Quality Assurance System

Certificate No.:  
250861-2017-CE-BRA-NA-PS Rev. 0.0

Project No.:  
PRJC-552950-2016-MSL-BRA

Valid Until:  
15 November 2023

<p>Tapered Bioneck TRI NP 3.5 x 13mm Tapered Bioneck TRI NP 3.5 x 16mm Tapered Bioneck TRI NP 4.3 x 8mm Tapered Bioneck TRI NP 4.3 x 10mm Tapered Bioneck TRI NP 4.3 x 11.5mm Tapered Bioneck TRI NP 4.3 x 13mm Tapered Bioneck TRI NP 4.3 x 16mm Tapered Bioneck TRI RP 4.3 x 8mm Tapered Bioneck TRI RP 4.3 x 10mm Tapered Bioneck TRI RP 4.3 x 11.5mm Tapered Bioneck TRI RP 4.3 x 13mm Tapered Bioneck TRI RP 4.3 x 16mm Tapered Bioneck TRI UP 5.0 x 8mm Tapered Bioneck TRI UP 5.0 x 10mm Tapered Bioneck TRI UP 5.0 x 11.5mm Tapered Bioneck TRI UP 5.0 x 13mm Tapered Bioneck TRI UP 5.0 x 16mm Tapered Bioneck TRI WP 5.0 x 8mm Tapered Bioneck TRI WP 5.0 x 10mm Tapered Bioneck TRI WP 5.0 x 13mm Tapered Bioneck TRI WP 5.0 x 16mm Cylindrical Dynamic CMI NP 3.5 x 8.5mm Cylindrical Dynamic CMI NP 3.5 x 10mm Cylindrical Dynamic CMI NP 3.5 x 11.5mm Cylindrical Dynamic CMI NP 3.5 x 13mm Cylindrical Dynamic CMI NP 3.5 x 15mm Cylindrical Dynamic CMI RP 4.3 x 8.5mm Cylindrical Dynamic CMI RP 4.3 x 10mm Cylindrical Dynamic CMI RP 4.3 x 11.5mm Cylindrical Dynamic CMI RP 4.3 x 13mm Cylindrical Dynamic CMI RP 4.3 x 15mm Cylindrical Dynamic CMI RP 5.0 x 8.5mm Cylindrical Dynamic CMI RP 5.0 x 10mm Cylindrical Dynamic CMI RP 5.0 x 11.5mm Cylindrical Dynamic CMI RP 5.0 x 13mm Cylindrical Dynamic CMI RP 5.0 x 15mm Tapered Single CMI NP 3.5 x 8mm Tapered Single CMI NP 3.5 x 10mm Tapered Single CMI NP 3.5 x 11.5mm Tapered Single CMI NP 3.5 x 13mm Tapered Single CMI NP 3.5 x 16mm Tapered Single CMI RP 4.3 x 8mm Tapered Single CMI RP 4.3 x 10mm</p>
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## EC Certificate Full Quality Assurance System

Certificate No.:  
250861-2017-CE-BRA-NA-PS Rev. 0.0

Project No.:  
PRJC-552950-2016-MSL-BRA

Valid Until:  
15 November 2023

	<p>Tapered Single CMI RP 4.3 x 11.5mm  Tapered Single CMI RP 4.3 x 13mm  Tapered Single CMI RP 4.3 x 16mm  Tapered Single CMI RP 5.0 x 8mm  Tapered Single CMI RP 5.0 x 10mm  Tapered Single CMI RP 5.0 x 11.5mm  Tapered Single CMI RP 5.0 x 13mm  Tapered Single CMI RP 5.0 x 16mm  Kort HEX NP 4.0 x 5.5mm  Kort HEX NP 4.0 x 7.0mm  Kort HEX RP 5.0 x 5.5mm  Kort HEX RP 5.0 x 7.0mm  Kort CMI Plus NP 3.5 x 5.5mm  Kort CMI Plus NP 3.5 x 7.0mm  Kort CMI Plus NP 4.3 x 5.5mm  Kort CMI Plus NP 4.3 x 7.0mm  Kort CMI Plus NP 5.0 x 5.5mm  Kort CMI Plus NP 5.0 x 7.0mm  Cylindrical Exakort HI 3.3 x 8mm  Cylindrical Exakort HI 3.3 x 10mm  Cylindrical Exakort HI 3.3 x 11.5mm  Cylindrical Exakort HI 3.3 x 13mm  Cylindrical Exakort HI 3.3 x 15mm  Cylindrical Exakort HI 3.8 x 8mm  Cylindrical Exakort HI 3.8 x 10mm  Cylindrical Exakort HI 3.8 x 11.5mm  Cylindrical Exakort HI 3.8 x 13mm  Cylindrical Exakort HI 3.8 x 15mm  Cylindrical Exakort HI 4.2 x 8mm  Cylindrical Exakort HI 4.2 x 10mm  Cylindrical Exakort HI 4.2 x 11.5mm  Cylindrical Exakort HI 4.2 x 13mm  Cylindrical Exakort HI 4.2 x 15mm</p>	
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The complete list of devices is filed with the Notified Body



## EC Certificate Full Quality Assurance System

Certificate No.:  
**250861-2017-CE-BRA-NA-PS Rev. 0.0**

Project No.:  
**PRJC-552950-2016-MSL-BRA**

Valid Until:  
**15 November 2023**

### Sites covered by this certificate

Site Name	Address
DÉRIG INDÚSTRIA E COMÉRCIO DE MATERIAIS MÉDICO-ODONTOLÓGICOS LTDA. EPP	Rua Lapa, 479 – Chácara Marco 06419-020 Barueri/SP - Brazil

### EU Representative

EXAKTUS-Oral Rehabilitation Material Ltda.

Address: Rua de Laborim, 68, Vila Nova Gaia, Porto, Portugal-CEP 4430-128



## EC Certificate Full Quality Assurance System

Certificate No.:  
**250861-2017-CE-BRA-NA-PS Rev. 0.0**

Project No.:  
**PRJC-552950-2016-MSL-BRA**

Valid Until:  
**15 November 2023**

### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate





## APPENDIX TO EC CERTIFICATE

Certificate no.:  
250861-2017-CE-BRA-NA-PS Rev 1.0

Valid Until:  
15 November 2023

This is an Appendix issued to EC Certificate issued for manufacturer:  
**DÉRIG INDÚSTRIA E COMÉRCIO DE MATERIAIS MÉDICO-  
ODONTOLÓGICOS LTDA. EPP**

originally issued in compliance with:  
**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Editorial changes - typo in EU Representative.

<b>EU Representative</b>
EXAKTUS-Oral Rehabilitation Material Ltda. Address: Rua de Laborim, 68, Vila Nova Gaia, Porto, Portugal-CEP 4430-128

Appendix History		
Revision	Description	Issued Date
0.0	Editorial changes - typo in EU Representative.	01 December 2021

Place and date:  
Havik, 01 December 2021



For the issuing office:  
DNV Product Assurance AS - Notified Body 2460  
Vertavaelen 3, 1363 Havik, Norway

Hazem Tinsawi  
Technical Reviewer

Notified Body 2460: DNV Product Assurance AS, Vertavaelen 3, 1363 Havik, Norway, Tel +47 07 57 88 00, www.dnv.com



## EC CERTIFICATE

### Full Quality Assurance System

Certificate No.:	Project No.:	Valid U/MS
250881-2017-CE-80A-NA-PS Rev. 1.0	PRUC-052850-2016-MSL-BRA	13 November 2023

This is to certify that the quality system of:

### **DÉRIG INDÚSTRIA E COMÉRCIO DE MATERIAIS MÉDICO-ODONTOLÓGICOS LTDA. EPP**

Rua Lapa, 479 – Chácaras Marco - 06419-020 – Barueri - SP - Brazil

For design, production and final product inspection/testing of:  
**DENTAL IMPLANTS AND COMPONENTS**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II  
excluding section 4 of Council Directive 93/42/EEC on Medical  
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
Havik, 24 May 2021

For the issuing office:  
Notified Body 2460  
DNV Product Assurance AS



Mariann Jeremiassen  
Principal Assessor

Notice: This Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460 DNV Product Assurance AS, Veitstovnen 3, 1365 Høvik, Norway. Tel +47 67 87 88 00. [www.dnv.com](http://www.dnv.com)

EP-4-5-1-4ECC-02 rev.0



Certificate No.: 256741-2015-CE-BRA-NL-PS Rev.: 1.0  
Place and date: Havik, 24 May 2021

#### Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

#### Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	16 November 2018
1.0	<b>Format change of certificate template. Extension in scope - new products (in bold) added.</b>	<b>24 May 2021</b>

#### Products covered by this Certificate:

Product Description	Product Name	Class
DENTAL IMPLANT	Cylindrical Biondent HEX NP 3.3 x 8.5mm	IIb
	Cylindrical Biondent HEX NP 3.3 x 10mm	
	Cylindrical Biondent HEX NP 3.3 x 11.5mm	
	Cylindrical Biondent HEX NP 3.3 x 13mm	
	Cylindrical Biondent HEX NP 3.3 x 15mm	
	Cylindrical Biondent HEX RP 3.75 x 8.5mm	
	Cylindrical Biondent HEX RP 3.75 x 10mm	
	Cylindrical Biondent HEX RP 3.75 x 11.5mm	
	Cylindrical Biondent HEX RP 3.75 x 13mm	
	Cylindrical Biondent HEX RP 3.75 x 15mm	
	Cylindrical Biondent HEX RP 4.0 x 8.5mm	
	Cylindrical Biondent HEX RP 4.0 x 10mm	
	Cylindrical Biondent HEX RP 4.0 x 11.5mm	
	Cylindrical Biondent HEX RP 4.0 x 13mm	
	Cylindrical Biondent HEX RP 4.0 x 15mm	
	Cylindrical Biondent HEX RP 4.0 x 17mm	
	Cylindrical Biondent HEX UP 5.0 x 8.5mm	
	Cylindrical Biondent HEX UP 5.0 x 10mm	
	Cylindrical Biondent HEX UP 5.0 x 11.5mm	
	Cylindrical Biondent HEX UP 5.0 x 13mm	
	Cylindrical Biondent HEX UP 5.0 x 15mm	
	Tapered Biondent TRI NP 3.5 x 8mm	
	Tapered Biondent TRI NP 3.5 x 10mm	
	Tapered Biondent TRI NP 3.5 x 11.5mm	
	Tapered Biondent TRI NP 3.5 x 13mm	
	Tapered Biondent TRI NP 3.5 x 16mm	
	Tapered Biondent TRI NP 4.3 x 8mm	
	Tapered Biondent TRI NP 4.3 x 10mm	
	Tapered Biondent TRI NP 4.3 x 11.5mm	
	Tapered Biondent TRI NP 4.3 x 13mm	
	Tapered Biondent TRI NP 4.3 x 16mm	
	Tapered Biondent TRI RP 4.3 x 8mm	
	Tapered Biondent TRI RP 4.3 x 10mm	
Tapered Biondent TRI RP 4.3 x 11.5mm		
Tapered Biondent TRI RP 4.3 x 13mm		
Tapered Biondent TRI RP 4.3 x 16mm		
Tapered Biondent TRI UP 5.0 x 8mm		
Tapered Biondent TRI UP 5.0 x 10mm		
Tapered Biondent TRI UP 5.0 x 11.5mm		

Notex: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2462: DNV Product Assurance AS, Veitstasjonen 3, 1383 Havik, Norway. Tel: +47 97 97 89 95. [www.dnv.com](https://www.dnv.com)

ICPA-5-11-MDD-02 rev/1

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Certificate No.: 238741-2019-CE-SRA-NMPS Rev: 1.0  
Place and date: Hovik, 24 May 2021

DENTAL IMPLANT	<p>                     Tapered Bioneck TRI UP 5.0 x 13mm                      Tapered Bioneck TRI UP 5.0 x 16mm                      Tapered Bioneck TRI WP 5.0 x 8mm                      Tapered Bioneck TRI WP 5.0 x 10mm                      Tapered Bioneck TRI WP 5.0 x 13mm                      Tapered Bioneck TRI WP 5.0 x 16mm                      Cylindrical Dynamic CMI NP 3.5 x 8.5mm                      Cylindrical Dynamic CMI NP 3.5 x 10mm                      Cylindrical Dynamic CMI NP 3.5 x 11.5mm                      Cylindrical Dynamic CMI NP 3.5 x 13mm                      Cylindrical Dynamic CMI NP 3.5 x 15mm                      Cylindrical Dynamic CMI RP 4.3 x 8.5mm                      Cylindrical Dynamic CMI RP 4.3 x 10mm                      Cylindrical Dynamic CMI RP 4.3 x 11.5mm                      Cylindrical Dynamic CMI RP 4.3 x 13mm                      Cylindrical Dynamic CMI RP 4.3 x 15mm                      Cylindrical Dynamic CMI RP 5.0 x 8.5mm                      Cylindrical Dynamic CMI RP 5.0 x 10mm                      Cylindrical Dynamic CMI RP 5.0 x 11.5mm                      Cylindrical Dynamic CMI RP 5.0 x 13mm                      Cylindrical Dynamic CMI RP 5.0 x 15mm                      Tapered Single CMI NP 3.5 x 8mm                      Tapered Single CMI NP 3.5 x 10mm                      Tapered Single CMI NP 3.5 x 11.5mm                      Tapered Single CMI NP 3.5 x 13mm                      Tapered Single CMI NP 3.5 x 16mm                      Tapered Single CMI RP 4.3 x 8mm                      Tapered Single CMI RP 4.3 x 10mm                      Tapered Single CMI RP 4.3 x 11.5mm                      Tapered Single CMI RP 4.3 x 13mm                      Tapered Single CMI RP 4.3 x 16mm                      Tapered Single CMI RP 5.0 x 8mm                      Tapered Single CMI RP 5.0 x 10mm                      Tapered Single CMI RP 5.0 x 11.5mm                      Tapered Single CMI RP 5.0 x 13mm                      Tapered Single CMI RP 5.0 x 16mm                      Kort HEX NP 4.0 x 5.5mm                      Kort HEX NP 4.0 x 7.0mm                      Kort HEX RP 5.0 x 5.5mm                      Kort HEX RP 5.0 x 7.0mm                      Kort CMI Plus NP 3.5 x 5.5mm                      Kort CMI Plus NP 3.5 x 7.0mm                      Kort CMI Plus NP 4.3 x 5.5mm                      Kort CMI Plus NP 4.3 x 7.0mm                      Kort CMI Plus NP 5.0 x 5.5mm                      Kort CMI Plus NP 5.0 x 7.0mm                      Cylindrical Exakort HI 3.3 x 8mm                      Cylindrical Exakort HI 3.3 x 10mm                      Cylindrical Exakort HI 3.3 x 11.5mm                      Cylindrical Exakort HI 3.3 x 13mm                      Cylindrical Exakort HI 3.3 x 15mm                      Cylindrical Exakort HI 3.8 x 8mm                      Cylindrical Exakort HI 3.8 x 10mm                      Cylindrical Exakort HI 3.8 x 11.5mm                      Cylindrical Exakort HI 3.8 x 13mm                      Cylindrical Exakort HI 3.8 x 15mm                      Cylindrical Exakort HI 4.2 x 8mm                      Cylindrical Exakort HI 4.2 x 10mm                      Cylindrical Exakort HI 4.2 x 11.5mm                      Cylindrical Exakort HI 4.2 x 13mm                      Cylindrical Exakort HI 4.2 x 15mm                 </p>	lib
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Notice: This Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 3480: DNV Product Assurance AS, Verhovenski 3, 1303 Hovik, Norway, Tel: +47 67 51 98 00, [www.dnv.com](http://www.dnv.com)

ICP-4-S-11-MDD-G, rev. 0

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Certificate No.: 265741-2019-GE-0RA-NA-PS Rev. 1.0  
Place and date: Hovik, 24 May 2021

<p><b>DENTAL COMPONENT - CoCr</b></p>	<p>Ucla HEX NP R Ucla HEX NP AR Ucla HEX RP-UP R Ucla HEX RP-UP AR Ucla HEX WP R Ucla HEX WP AR Ucla CMI NP R Ucla CMI NP AR Ucla TRI NP R Ucla TRI NP AR Ucla TRI RP-UP R Ucla TRI RP-UP AR Ucla TRI WP R Ucla TRI WP AR Ucla HI AR Ucla HI R Coping MPC</p>	<p><b>IIB</b></p>
<p><b>DENTAL COMPONENT - Ti</b></p>	<p>Profile Abutment HEX NP C1 Profile Abutment HEX NP C2 Profile Abutment HEX NP C3 Profile Abutment HEX NP C4 Profile Abutment HEX RP-UP C1 Profile Abutment HEX RP-UP C2 Profile Abutment HEX RP-UP C3 Profile Abutment HEX RP-UP C4 Profile Abutment TRI NP C0,5 Profile Abutment TRI NP C1 Profile Abutment TRI NP C2 Profile Abutment TRI NP C3 Profile Abutment TRI NP C4 Profile Abutment TRI RP-UP C0,5 Profile Abutment TRI RP-UP C1 Profile Abutment TRI RP-UP C2 Profile Abutment TRI RP-UP C3 Profile Abutment TRI RP-UP C4 Profile Abutment TRI WP C2 Profile Abutment TRI WP C3 Profile Abutment CMI NP C 1,0 Profile Abutment CMI NP C 2,0 Profile Abutment CMI NP C 3,0 Profile Abutment CMI NP C 4,0 Profile Abutment CMI RP C 1,0 Profile Abutment CMI RP C 2,0 Profile Abutment CMI RP C 3,0 Profile Abutment CMI RP C 4,0 Profile Abutment CMI 3,0 C 0,5 Profile Abutment CMI 3,0 C 1,0 Profile Abutment CMI 3,0 C 2,0 Profile Abutment CMI 3,0 C 3,0 Profile Abutment CMI 3,0 C 4,0 Fixing Screw HEX NP / hex 1,2 Fixing Screw HEX NP / hex 1,28 Fixing Screw HEX RP-UP / hex 1,2 Fixing Screw HEX RP-UP / hex 1,28 Fixing Screw HEX RP-UP / grip Fixing Screw HEX WP / hex 1,2 Fixing Screw TRI NP / hex 1,2 Fixing Screw TRI NP / hex 1,28 Fixing Screw TRI NP / grip Fixing Screw TRI RP-UP-WP / hex 1,2</p>	<p><b>IIB</b></p>

Note: This Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2400: DNV Product Assurance AS, Vestrevesletta 3, 1383 Hovik, Norway. Tel: +47 67 61 88 00, [nao@dnv.com](mailto:nao@dnv.com)

ICP-4-S-1-MDD-G, rev.0

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Certificate No.: 265741-2019-GE-0RA-NA-PS Rev. 1.0  
Place and date: Hovik, 24 May 2021

<p><b>DENTAL COMPONENT - CoCr</b></p>	<p>Ucla HEX NP R Ucla HEX NP AR Ucla HEX RP-UP R Ucla HEX RP-UP AR Ucla HEX WP R Ucla HEX WP AR Ucla CMI NP R Ucla CMI NP AR Ucla TRI NP R Ucla TRI NP AR Ucla TRI RP-UP R Ucla TRI RP-UP AR Ucla TRI WP R Ucla TRI WP AR Ucla HI AR Ucla HI R Coping MPC</p>	<p><b>IIB</b></p>
<p><b>DENTAL COMPONENT - Ti</b></p>	<p>Profile Abutment HEX NP C1 Profile Abutment HEX NP C2 Profile Abutment HEX NP C3 Profile Abutment HEX NP C4 Profile Abutment HEX RP-UP C1 Profile Abutment HEX RP-UP C2 Profile Abutment HEX RP-UP C3 Profile Abutment HEX RP-UP C4 Profile Abutment TRI NP C0,5 Profile Abutment TRI NP C1 Profile Abutment TRI NP C2 Profile Abutment TRI NP C3 Profile Abutment TRI NP C4 Profile Abutment TRI RP-UP C0,5 Profile Abutment TRI RP-UP C1 Profile Abutment TRI RP-UP C2 Profile Abutment TRI RP-UP C3 Profile Abutment TRI RP-UP C4 Profile Abutment TRI WP C2 Profile Abutment TRI WP C3 Profile Abutment CMI NP C 1,0 Profile Abutment CMI NP C 2,0 Profile Abutment CMI NP C 3,0 Profile Abutment CMI NP C 4,0 Profile Abutment CMI RP C 1,0 Profile Abutment CMI RP C 2,0 Profile Abutment CMI RP C 3,0 Profile Abutment CMI RP C 4,0 Profile Abutment CMI 3,0 C 0,5 Profile Abutment CMI 3,0 C 1,0 Profile Abutment CMI 3,0 C 2,0 Profile Abutment CMI 3,0 C 3,0 Profile Abutment CMI 3,0 C 4,0 Fixing Screw HEX NP / hex 1,2 Fixing Screw HEX NP / hex 1,28 Fixing Screw HEX RP-UP / hex 1,2 Fixing Screw HEX RP-UP / hex 1,28 Fixing Screw HEX RP-UP / grip Fixing Screw HEX WP / hex 1,2 Fixing Screw TRI NP / hex 1,2 Fixing Screw TRI NP / hex 1,28 Fixing Screw TRI NP / grip Fixing Screw TRI RP-UP-WP / hex 1,2</p>	<p><b>IIB</b></p>

Notice: This Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2400: DNV Product Assurance AS, Vestvassveien 3, 1383 Hovik, Norway. Tel: +47 67 61 88 00, [nao@dnv.com](mailto:nao@dnv.com)

ICP-4-S-1-MDD-G, rev.0

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Certificate No.: 2021/1-2019-CE-ENEA-NA-PE Rev: 1.0  
Place and date: Hovik, 24 May 2021

<p>DENTAL COMPONENT - TI</p>	<p>                     Esthetic Abutment CMI NP C2,0                      Esthetic Abutment CMI NP C3,0                      Esthetic Abutment CMI NP C4,0                      Esthetic Abutment CMI RP C1,0                      Esthetic Abutment CMI RP C2,0                      Esthetic Abutment CMI RP C3,0                      Esthetic Abutment CMI RP C4,0                      Esthetic Abutment CMI 3,0 C1,0                      Esthetic Abutment CMI 3,0 C2,0                      Esthetic Abutment CMI 3,0 C3,0                      Esthetic Abutment CMI 3,0 C4,0                      Esthetic Abutment 15° HEX NP C1                      Esthetic Abutment 15° HEX NP C2                      Esthetic Abutment 15° HEX NP C3                      Esthetic Abutment 15° HEX RP-UP C1                      Esthetic Abutment 15° HEX RP-UP C2                      Esthetic Abutment 15° HEX RP-UP C3                      Esthetic Abutment 15° TRS NP C0,5                      Esthetic Abutment 15° TRS NP C1                      Esthetic Abutment 15° TRS NP C2                      Esthetic Abutment 15° TRS RP-UP C1                      Esthetic Abutment 15° TRS RP-UP C2                      Esthetic Abutment 15° CMI NP C1,0                      Esthetic Abutment 15° CMI NP C2,0                      Esthetic Abutment 15° CMI NP C3,0                      Esthetic Abutment 15° CMI NP C4,0                      Esthetic Abutment 15° CMI RP C1,0                      Esthetic Abutment 15° CMI RP C2,0                      Esthetic Abutment 15° CMI RP C3,0                      Esthetic Abutment 15° CMI RP C4,0                      Esthetic Abutment 15° CMI 3,0 C1,0                      Esthetic Abutment 15° CMI 3,0 C2,0                      Esthetic Abutment 15° CMI 3,0 C3,0                      Esthetic Abutment 15° CMI 3,0 C4,0                      Temporary Abutment HEX NP R                      Temporary Abutment HEX RP-UP R                      Temporary Abutment TRI NP R                      Temporary Abutment TRI RP-UP R                      Temporary Abutment CMI NP R                      Temporary Abutment CMI 3,0 R                      Temporary Abutment HEX NP AR                      Temporary Abutment HEX RP-UP AR                      Temporary Abutment TRI NP AR                      Temporary Abutment TRI RP-UP AR                      Temporary Abutment TRI WP AR                      Abutment CMI NP AR                      Temporary Abutment CMI 3,0 AR                      Temporary Abutment Plus TRI NP R                      Temporary Abutment Plus TRI NP AR                      Temporary Coping MPC                      Coping Screw MPC / hex 1,2                      Coping Screw MPC / hex 1,28                      Coping Screw MPC / grip                      Impression Copings HEX NP Open Tray / hex 1,2                      Impression Copings HEX RP-UP Open Tray / hex 1,2                      Impression Copings HEX WP Open Tray / hex 1,2                      Impression Copings TRI NP Open Tray / hex 1,2                      Impression Copings TRI RP-UP Open Tray / hex 1,2                      Impression Copings MPC Open Tray / hex 1,2                      Impression Copings PC Open Tray / hex 1,2                      Impression Copings HEX NP Closed Tray / hex 1,2                 </p>	<p>lib</p>
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Note: This Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may result in this Certificate being

NOTIFIED BODY 2400 DNV Product Assurance AS, Vestrelands 1, 1303 Hovik, Norway, Tel +47 67 67 89 00, [www.dnv.com](http://www.dnv.com)

ICP-A&L1A00-01 rev.0

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Certificate No.: 20274-1-2019-CE-BSA-NA-PO Rev. 1.0  
Place and date: Trondheim, 26 May 2021

DENTAL COMPONENT - TI	Impression Copings HEX RP-UP Closed Tray / hex 1,2 Impression Copings HEX WP Closed Tray / hex 1,2 Impression Copings TRI NP Closed Tray / hex 1,2 Impression Copings TRI RP-UP Closed Tray / hex 1,2 Impression Copings PC Closed Tray / hex 1,2 Healing Cap MPC / hex 1,2 Healing Cap MPC SM Healing Cap MPC LG Healing Cap MPC Esthetic SM Healing Cap MPC Esthetic LG Healing Cap PC / hex 1,2 Abutment Simple CMI NP 4 C 1,0 SM Abutment Simple CMI NP 4 C 2,0 SM Abutment Simple CMI NP 4 C 3,0 SM Abutment Simple CMI NP 4 C 4,0 SM Abutment Simple CMI NP 6 C 1,0 SM Abutment Simple CMI NP 6 C 2,0 SM Abutment Simple CMI NP 6 C 3,0 SM Abutment Simple CMI NP 6 C 4,0 SM Impression Copings CMI NP OPEN TRAY Impression Copings CMI RP OPEN TRAY Impression Copings CMI 3,0 OPEN TRAY Impression Copings CMI NP Closed Tray Impression Copings CMI RP Closed Tray Impression Copings CMI 3,0 Closed Tray Profile Abutment HI C1 Profile Abutment HI C2 Profile Abutment HI C3 Temporary Abutment HI AR Temporary Abutment HI R Impression Copings Implant HI Open Tray Impression Copings Implant HI Closed Tray Fixing Screw HI / hex 1,2 Profile Abutment15° HI C1 Profile Abutment25° HI C1 Profile Abutment15° HI C2 Profile Abutment25° HI C2 Profile Abutment15° HI C3 Profile Abutment25° HI C3 Esthetic Abutment 15° HI C1 Esthetic Abutment 15° HI C2 Esthetic Abutment 15° HI C3	lib
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The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

Site Name	Address
DÉRIG INDÚSTRIA E COMÉRCIO DE MATERIAIS MÉDICO-ODONTOLÓGICOS LTDA. EPP	Rua Lapa, 479 – Chácara Marco - 06419-020 – Barueri - SP - Brazil

**EU Representative**

Cinterqual LDA, Travessa da Anunciada, 10 – 2 Esq-F. 2900-238.  
Setúbal – Portugal. Phone: +351 265 238 237

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY: 2462 DNV Product Assurance AS, Varhaugen 1, 1363 Hovik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

EP4441-M01-07, rev 8

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Certificate No.: 286741-2019-CE-ERA-NA-PS Rev. 1.0  
Place and date: Hovik, 24 May 2021

### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system, the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2481 DNV Product Assurance AS, Veitstovnen 3, 1383 Hovik, Norway, Tel +47 67 67 88 00, [www.dnv.com](http://www.dnv.com)

CPA-571-MCO-01 rev.3

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## APPENDIX TO EC CERTIFICATE

Certificate no.:  
250661-2017-CE-GRANA-P3 Rev 1.0

Valid Until:  
18 November 2023

This is an Appendix issued to EC Certificate issued for manufacturer:  
**DÉRIG INDÚSTRIA E COMÉRCIO DE MATERIAIS MÉDICO-  
ODONTOLÓGICOS LTDA. EPP**

originally issued in compliance with:  
**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

### Scope Reduction of TI Components

Products covered by this Certificate: (replaces information on certificate)		
Product Description	Product Name	Class
DENTAL IMPLANT	Cylindrical Biodent HEX NP 3.3 x 8.5mm Cylindrical Biodent HEX NP 3.3 x 10mm Cylindrical Biodent HEX NP 3.3 x 11.5mm Cylindrical Biodent HEX NP 3.3 x 13mm Cylindrical Biodent HEX NP 3.3 x 15mm Cylindrical Biodent HEX RP 3.75 x 8.5mm Cylindrical Biodent HEX RP 3.75 x 10mm Cylindrical Biodent HEX RP 3.75 x 11.5mm Cylindrical Biodent HEX RP 3.75 x 13mm Cylindrical Biodent HEX RP 3.75 x 15mm Cylindrical Biodent HEX RP 4.0 x 8.5mm Cylindrical Biodent HEX RP 4.0 x 10mm Cylindrical Biodent HEX RP 4.0 x 11.5mm Cylindrical Biodent HEX RP 4.0 x 13mm Cylindrical Biodent HEX RP 4.0 x 15mm Cylindrical Biodent HEX RP 4.0 x 17mm Cylindrical Biodent HEX UP 5.0 x 8.5mm Cylindrical Biodent HEX UP 5.0 x 10mm Cylindrical Biodent HEX UP 5.0 x 11.5mm Cylindrical Biodent HEX UP 5.0 x 13mm Cylindrical Biodent HEX UP 5.0 x 15mm Tapered Bioneck TRI NP 3.5 x 8mm Tapered Bioneck TRI NP 3.5 x 10mm Tapered Bioneck TRI NP 3.5 x 11.5mm Tapered Bioneck TRI NP 3.5 x 13mm Tapered Bioneck TRI NP 3.5 x 16mm	IIb

Place and date:  
Havik, 11 May 2022



For the issuing office:  
DNV Product Assurance AS - Notified Body 2460  
Verftasveien 3, 1363 Havik, Norway

Hazem Tinsae  
Technical Reviewer

Notified Body 2460: DNV Product Assurance AS, Verftasveien 3, 1363 Havik, Norway, Tel +47 97 57 88 00, www.dnv.com



Certificate no.: 250801-2017-CE-8RO-NA-PS Rev.1  
Place and date: Havelk, 11 May 2022

DENTAL IMPLANT	<p>Tapered Bioneck TRI NP 4.3 x 8mm Tapered Bioneck TRI NP 4.3 x 10mm Tapered Bioneck TRI NP 4.3 x 11.5mm Tapered Bioneck TRI NP 4.3 x 13mm Tapered Bioneck TRI NP 4.3 x 16mm Tapered Bioneck TRI RP 4.3 x 8mm Tapered Bioneck TRI RP 4.3 x 10mm Tapered Bioneck TRI RP 4.3 x 11.5mm Tapered Bioneck TRI RP 4.3 x 13mm Tapered Bioneck TRI RP 4.3 x 16mm Tapered Bioneck TRI UP 5.0 x 8mm Tapered Bioneck TRI UP 5.0 x 10mm Tapered Bioneck TRI UP 5.0 x 11.5mm Tapered Bioneck TRI UP 5.0 x 13mm Tapered Bioneck TRI UP 5.0 x 16mm Tapered Bioneck TRI WP 5.0 x 8mm Tapered Bioneck TRI WP 5.0 x 10mm Tapered Bioneck TRI WP 5.0 x 13mm Tapered Bioneck TRI WP 5.0 x 16mm Cylindrical Dynamic CMI NP 3.5 x 8.5mm Cylindrical Dynamic CMI NP 3.5 x 10mm Cylindrical Dynamic CMI NP 3.5 x 11.5mm Cylindrical Dynamic CMI NP 3.5 x 13mm Cylindrical Dynamic CMI NP 3.5 x 15mm Cylindrical Dynamic CMI RP 4.3 x 8.5mm Cylindrical Dynamic CMI RP 4.3 x 10mm Cylindrical Dynamic CMI RP 4.3 x 11.5mm Cylindrical Dynamic CMI RP 4.3 x 13mm Cylindrical Dynamic CMI RP 4.3 x 15mm Cylindrical Dynamic CMI RP 5.0 x 8.5mm Cylindrical Dynamic CMI RP 5.0 x 10mm Cylindrical Dynamic CMI RP 5.0 x 11.5mm Cylindrical Dynamic CMI RP 5.0 x 13mm Cylindrical Dynamic CMI RP 5.0 x 15mm Tapered Single CMI NP 3.5 x 8mm Tapered Single CMI NP 3.5 x 10mm Tapered Single CMI NP 3.5 x 11.5mm Tapered Single CMI NP 3.5 x 13mm Tapered Single CMI NP 3.5 x 16mm Tapered Single CMI RP 4.3 x 8mm Tapered Single CMI RP 4.3 x 10mm Tapered Single CMI RP 4.3 x 11.5mm Tapered Single CMI RP 4.3 x 13mm Tapered Single CMI RP 4.3 x 16mm Tapered Single CMI RP 5.0 x 8mm Tapered Single CMI RP 5.0 x 10mm Tapered Single CMI RP 5.0 x 11.5mm Tapered Single CMI RP 5.0 x 13mm Tapered Single CMI RP 5.0 x 16mm Kort HEX NP 4.0 x 5.5mm Kort HEX NP 4.0 x 7.0mm Kort HEX RP 5.0 x 5.5mm Kort HEX RP 5.0 x 7.0mm Kort CMI Plus NP 3.5 x 5.5mm Kort CMI Plus NP 3.5 x 7.0mm Kort CMI Plus NP 4.3 x 5.5mm Kort CMI Plus NP 4.3 x 7.0mm Kort CMI Plus NP 5.0 x 5.5mm Kort CMI Plus NP 5.0 x 7.0mm</p>	lib
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Certificate no.: 250001-2017-CO-BRA-NA-PS Rev.1  
Place and date: Havik, 11 May 2022

DENTAL IMPLANT	Cylindrical Exakort HI 3.3 x 8mm Cylindrical Exakort HI 3.3 x 10mm Cylindrical Exakort HI 3.3 x 11.5mm Cylindrical Exakort HI 3.3 x 13mm Cylindrical Exakort HI 3.3 x 15mm Cylindrical Exakort HI 3.6 x 8mm Cylindrical Exakort HI 3.6 x 10mm Cylindrical Exakort HI 3.6 x 11.5mm Cylindrical Exakort HI 3.6 x 13mm Cylindrical Exakort HI 3.6 x 15mm Cylindrical Exakort HI 4.2 x 8mm Cylindrical Exakort HI 4.2 x 10mm Cylindrical Exakort HI 4.2 x 11.5mm Cylindrical Exakort HI 4.2 x 13mm Cylindrical Exakort HI 4.2 x 15mm	IIb
DENTAL COMPONENT - CoCr	Ucla HEX NP R Ucla HEX NP AR Ucla HEX RP-UP R Ucla HEX RP-UP AR Ucla HEX WP R Ucla HEX WP AR Ucla CMI NP R Ucla CMI NP AR Ucla TRI NP R Ucla TRI NP AR Ucla TRI RP-UP R Ucla TRI RP-UP AR Ucla TRI WP R Ucla TRI WP AR Ucla HI AR Ucla HI R Coping MPC	IIb
DENTAL COMPONENT - Ti	Profile Abutment HEX NP C1 Profile Abutment HEX NP C2 Profile Abutment HEX NP C3 Profile Abutment HEX NP C4 Profile Abutment HEX RP-UP C1 Profile Abutment HEX RP-UP C2 Profile Abutment HEX RP-UP C3 Profile Abutment HEX RP-UP C4 Profile Abutment TRI NP C0,5 Profile Abutment TRI NP C1 Profile Abutment TRI NP C2 Profile Abutment TRI NP C3 Profile Abutment TRI NP C4 Profile Abutment TRI RP-UP C0,5 Profile Abutment TRI RP-UP C1 Profile Abutment TRI RP-UP C2 Profile Abutment TRI RP-UP C3 Profile Abutment TRI RP-UP C4 Fixing Screw HEX NP / hex 1,2 Fixing Screw HEX RP-UP / hex 1,2 Fixing Screw HEX RP-UP / grip Fixing Screw TRI NP / hex 1,2 Fixing Screw TRI NP / grip Fixing Screw TRI RP-UP-WP / hex 1,2 Fixing Screw TRI RP-UP-WP / grip Fixing Screw BRK NP / hex 1,2 Fixing Screw BRK NP/grip	IIb



Certificate no.: 250851-2017-CE-BRA-NA-PS Rev.1  
Place and date: Havik, 11 May 2022

DENTAL COMPONENT - Ti	Esthetic Abutment HEX RP-UP C1 Esthetic Abutment HEX RP-UP C2 Esthetic Abutment HEX RP-UP C3 Esthetic Abutment TRI NP C0,5 Esthetic Abutment TRI NP C1 Esthetic Abutment TRI NP C2 Esthetic Abutment TRI NP C3 Esthetic Abutment TRI RP-UP C0,5 Esthetic Abutment TRI RP-UP C1 Esthetic Abutment TRI RP-UP C2 Esthetic Abutment TRI RP-UP C3 Esthetic Abutment 15° HEX NP C1 Esthetic Abutment 15° HEX NP C2 Esthetic Abutment 15° HEX NP C3 Esthetic Abutment 15° HEX RP-UP C1 Esthetic Abutment 15° HEX RP-UP C2 Esthetic Abutment 15° HEX RP-UP C3 Esthetic Abutment 15° TRI NP C0,5 Esthetic Abutment 15° TRI NP C1 Esthetic Abutment 15° TRI NP C2 Esthetic Abutment 15° TRI RP-UP C1 Esthetic Abutment 15° TRI RP-UP C2 Temporary Abutment HEX NP R Temporary Abutment HEX RP-UP R Temporary Abutment TRI NP R Temporary Abutment TRI RP-UP R Temporary Abutment HEX NP AR Temporary Abutment HEX RP-UP AR Temporary Abutment TRI NP AR Temporary Abutment TRI RP-UP AR Temporary Coping MPC Coping Screw MPC / hex 1,2 Coping Screw MPC / grip Impression Copings HEX NP Open Tray / hex 1,2 Impression Copings HEX RP-UP Open Tray / hex 1,2 Impression Copings TRI NP Open Tray / hex 1,2 Impression Copings TRI RP-UP Open Tray / hex 1,2 Impression Copings MPC Open Tray / hex 1,2 Impression Copings HEX NP Closed Tray / hex 1,2 Impression Copings HEX RP-UP Closed Tray / hex 1,2 Impression Copings TRI NP Closed Tray / hex 1,2 Impression Copings TRI RP-UP Closed Tray / hex 1,2 Healing Cap MPC / hex 1,2	lib
<b>Appendix History</b>		
<b>Revision</b>	<b>Description</b>	<b>Issued Date</b>
0	Editorial changes - typo in EU Representative.	09 November 2021
1	Scope reduction of Ti Components	11 May 2022