

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 680376
Issued To: Elos Medtech Pinol A/S
Engvej 33
Gorlose
3330
Denmark

In respect of:

The design and manufacture of dental devices (Drill Extender, Abutment Blank, Prosthetic Screw, Flexlink TiBase Kit, abutment and compatible screw, Elos Accurate Hybrid Base Kit, Elos Accurate API Bridge)

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2017-12-19**

Date: **2019-02-12**

Expiry Date: **2022-11-01**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date: **2019-02-12**
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Subcontractor:	Service(s) supplied
Acnis International 220 Rue Léon Blum Villeurbanne 69100 France	Crucial Supplier
Biomet 3i Dental Ibérica (VLC) c/ Islas Baleares, 50 Pol. Ind. Fuente del Jarro Paterna Valencia 46988 Spain	Manufacture
Dansk Teknologisk Institut Teknologiparken, Kongsvang Allé 29 Århus DK-8000 Denmark	Manufacture

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Subcontractor:	Service(s) supplied
EC Europ Coating GmbH Deutsch-Ordens-Straße 7 Hohenlockstedt 25551 Germany	Manufacture
L. Klein SA Längfeldweg 110 Chemin du Long-Champ Postfach 8358 Biel/Bienne 8 CH-2500 Switzerland	Crucial Supplier
Zapp Precision Metals GmbH Letmather Straße 69 Schwerte 58239 Germany	Crucial Supplier

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 680376**
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Date	Reference Number	Action
19 December 2017	8795642	First issue. Transfer from another Notified Body.
Current	8797114	Traceable to NB 0086.

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