EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 751241 R000

Manufacturer: Elos Medtech Pinol A/S

Address:
Engvej 33
Gørløse
3330
Denmark

Single Registration Number: DK-MF-000001915

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-10**

Current Issue Date: **2023-05-03**

Starting Validity Date: **2023-05-03**

Expiry Date: **2027-11-09**

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Dental Prosthetic Screw (Non-coated, Medicarb coated, Medigold coated)	Intended for fixation of prosthetic restorations to endosseous dental implants.
Dental Abutment Blank	Intended for dental prosthetic restorations. The Elos Abutment Blank is used as an interface between an endosseous dental implant and a dental restoration and will be attached to the implant using a prosthetic screw and attached to the dental restoration by cementing.
Dental Abutment	Intended for dental prosthetic restorations. The Elos Accurate® Hybrid Base™ is used as an interface between an endosseous dental implant and a dental restoration and will be attached to the implant using a prosthetic screw and attached to the dental restoration by cementing.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-11-10	3449021	Issued
Current	3868401	Supplemented – Addition of Medigold coated Prosthetic Screws. Amended – Addition of subcontractor for surface treatment of Medigold coated Prosthetic Screws.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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