

EC Certificate Production Quality Assurance System: Certificate GB19/964610

The management system of

Davis, Schottlander & Davis Ltd

Fifth Avenue, Letchworth, Hertfordshire, SG6 2WD, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 11 May 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits. Issue 9. Certified since 28 March 1997.

Certification is based on reports numbered GB/PC/ 07450

Authorised by

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Global Medical Devices Head of Notified Body

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 02

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SGS Belgium NV, Notified Body 1639 SGS House Noorderlaan 87 2030 Antwerp Belgium t+32 (0)3 545-48-48 f+32 (0)3 545-48-49 www.sgs.com

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Corrigendum to Certificate GB19/964610

Davis, Schottlander & Davis Ltd

Fifth Avenue, Letchworth, Hertfordshire, SG6 2WD, UK

Scope:

Temporary Crown & Bridge Materials: Quicktemp 2, Quicktemp Cosmetic, Quicktemp Cosmetic Glaze & Bond.

Crown & Bridge Materials: Ceramic Powder - Matchmaker Powders MC, enliven MC. Porcelains for bonding to metal alloys in the making of crowns & ancillary products. Bonding alloys non-precious Matchmate NP10 and NP20. Porcelains for bonding to zirconia copings or frameworks in the making of crowns, bridges & ancillary products Matchmaker ZR.

Restoratives & Cements: Opusfil Glass Ionomer, Opus silver powder, Opucem, Opus PCF. Light cured composite filling material - Ultra Fine Glass Composite, Quicktemp **Cosmetic Flowable Composite.** Amalgam Alloys – Starburst 45 Capsulated Alloy.

> Prosthetics: Acrylic Resin Teeth - Enigma, Enigmalife, Natura, & 4natur. **Prosthetics Materials:** Cobalt chromium alloy - Croform Excel S1. Acrylic Denture Base - Enigma High Base. Pegasus Pourable cold cure denture Base material. Pegasus Plus repair acrylic. Pegasus plus denture base, Pegasus Plus repair acrylic.

> > **Dental Surgery Rotary Instruments:** Non sterile diamond dental burs and polishers Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

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Certification and Business Enhancement Maatschappelijke Zetel/Siège Social: Noorderlaan 87 B-2030 Antwerpen/Anvers t +32 (0)3 545 48 48 f +32 (0)3 545 48 49 Member of the SGS Group www.be.sgs.com

RPR Antwerp VAT - BE 0404.882.750 Citibank BE87 5701 3412 5594

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This corrigendum is only valid together with accompanying 93/42/EEC certificate issue 9

Correction Date	<u>Correction</u>
Change approved by SGS on	Scope to remove duplication of
08 June 2021	device Pegasus Plus repair acrylic.
Change approved by SGS on 15 October 2021	Removal of device from scope:
	Porcelains for bonding to metal alloys in the making of crowns & ancillary products
Change approved by SGS on 14 February 2021	Addition of device back onto scope
	Porcelains for bonding to metal alloys in the making of crowns & ancillary products
Change approved by SGS on 09 May 2022	Correction of incorrect SGS approval date for the previous amendment from 14February 2021 to 14 February 2022

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