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 19 August 2020until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 28 March 1997 and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered GB/PC/ 07450

Authorised by

Pieter Weterings Certification Manager

SGS Belgium NV, Notified Body 1639

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## Davis, Schottlander & Davis Ltd

## Directive 93/42/EEC

on medical devices, Annex V

Issue 7

Detailed 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 aluminium oxide & zirconia copings or frameworks in the making of crowns, bridges & ancillary products
ALX and ZR.

Porcelains for making Ceramic Inlays, Onlays, Veneers and Crowns for Pressing to Metal – Matchmaker Press.

**Restoratives & Cements:** 

Enigma Colourtone.

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. Nylon Brushes & Bristle Brushes for RA handpieces

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required

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