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

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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Davis, Schottlander & Davis Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 9

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 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

Where the above scope includes Class IIb or Class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in Addition to this certificate to place the device on the market.