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 06 January 2020 until 30 November 2021
and remains valid subject to satisfactory surveillance audits.
Issue 2. 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

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Davis, Schottlander & Davis Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 2

Detailed scope

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:
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.
Enigma Colourtone.

Dental Surgery Rotary Instruments:
Nylon Brushes & Bristle Brushes for RA handpieces.

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 that device on the market.