Certificate GB20/965704

The quality management system of

Davis, Schottlander & Davis Ltd

Fifth Avenue Letchworth Garden City Hertfordshire SG6 2WD United Kingdom Facility number: F003834

has been assessed and certified as meeting the requirements of **MDSAP (ISO 13485:2016)**

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System Canada: Medical Device Regulations SOR/98-282, Part 1 USA: 21 CFR Part 803 - Medical Device Reporting ; 21 CFR Part 806 - Reports of Corrections and Removals ;

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing ; 21 CFR Part 820 - Quality System Regulation

For the following activities The Scope of Registration appears on page 2 of this certificate

This certificate is valid from Effective date 2023-04-20 until Expiry date 2026-04-19 and remains valid subject to satisfactory surveillance audits. Issue 4. Certified since 2020-04-21

Defander

Authorised by Geofrey De Visscher Head of Notified Body 1639

SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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Certificate GB20/965704, continued **Davis, Schottlander & Davis Ltd**

MDSAP (ISO 13485:2016)

Design and manufacture the following devices for the area of Dentistry:

Temporary Crown & Bridge Materials.

Crown & Bridge Materials: Ceramic Powder, and Porcelains for bonding to metal alloys in the making of crowns & ancillary products. Non-precious bonding alloys. Porcelains for bonding to zirconia copings or frameworks in the making of crowns, bridges & ancillary products

Restoratives & Cements: Light cured composite filling materials. Glass lonomer cement. Silver powder. Opusfil Glass lonomer, Opus silver powder, Opucem, Opus PCF Ultra Fine Glass Composite. Amalgam Alloys,

Prosthetics: Acrylic Resin Teeth

Prosthetics Materials: Cobalt chromium alloy. Acrylic Denture Base. Cold cure denture Base material. Denture base materials, Repair acrylic.

Dental Surgery Rotary Instruments: Non sterile diamond dental burs and polishers.



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