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

Corrigendum to Certificate GB19/96461

Davis, Schottlander & Davis Ltd

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

Directive 93/42/EEC

on medical devices, Annex V

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

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

LPMD5105 – Corrigendum to Certificate

DAVIS SCHOTTLANDER & DAVIS LTD
5TH AVENUE
LETCHWORTH GARDEN CITY
SG6 2WD
UK

22/05/2025

Confirmation Letter Reference: CLNB1639 - GBPC 07450

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

DAVIS SCHOTTLANDER & DAVIS LTD
FIFITH AVENUE
LETCHWORTH GARDEN CITY
SG6 2WD
UK
SRN: GB-MF-000035008

Authorised Representative:

SCHOTTLANDER (IRL) LTD
Suite 11, Parklands Office Park
Southern Cross Road
Bray Co. Wicklow Eire
SRN: IE-AR-000029625

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the

NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Pp[Sean Kelly]
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Veneering Ceramic 5052674MET-CERAM4T	Class IIa	Matchmaker Powders MC, enliven MC, Enliven Paste Opaque, Enliven Universal Stains, Propaque Paste Opaques Including Easee Pake, Matchmaker Pontic Fill	N/A	GB19/964610; NB1639
Acrylic Resin Teeth 5052674TEETH-CL2ASR	Class IIa	Acrylic Resin Teeth - Enigma, Enigmalife, Natura, & 4natur	N/A	GB19/964610; NB1639
Acrylic Denture Bases and Repair Materials 5052674DENT-BASEZ6	Class IIa	Acrylic Denture Base - Enigma High Base; Pegasus Pourable cold cure denture Base material; Pegasus Plus repair acrylic; Pegasus plus denture base.	N/A	GB19/964610; NB1639

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
29/05/2024	Version 1	Initial issue
20/03/2025	Version 2	Removal of Schottlander Ultra Fine Glass Composite 5052674CC-DENT-BASEUG from scope.
22/05/2025	Version 3	Removal of Quicktemp Cosmetic / Quicktemp 2 5052674TEMP-CROWN23 & Quicktemp Cosmetic Glaze and Bond 5052674G/B-TEMP-CROWNDD