

The management system of

Davis Schottlander & Davis Ltd

Fifth Avenue Letchworth Garden City, Herts SG6 2WD UK

AUTHORISED REP:

Schottlander (IRL) Ltd

Suite 11, Parklands Office Park, Southern Cross Road, Bray, Co. Wicklow, Eire

EC-DECLARATION OF CONFORMITY

Directive 93/42/EEC

Products in MDD Class IIa


It is hereby declared that the products listed below comply with the provisions of the EC Council Directive 93/42/EEC of June 14th 1993, concerning medical devices (MDD), Annex V, as amended by EC Council Directive 2007/47/EC under the supervision of Notified Body number 1639, SGS Belgium NV, SGS House, Noorderlaan 87 2030, Antwerp, Belgium.

Medical Device Name	BASIC UDI	GMDN Code	Rule
4natur Teeth	5052674TEETH-CL2ASR	38643	Rule 5
Croform Excel S1 Alloy	5052674CO-CHROME-ALLOYC4	35857	Rule 5
Enigma High Base Denture base	5052674DENT-BASEZ6	63591	Rule 5
Engima Teeth	5052674TEETH-CL2ASR	38643	Rule 5
enigmalive Teeth	5052674TEETH-CL2ASR	38643	Rule 5
enliven MC Porcelain	5052674MET-CERAM4T	16187	Rule 8
enliven MC Porcelain Kit	5052674MET-CERAM4T	44727	Rule 8
enliven Universal Stain Kit	5052674MET-CERAM4T	44727	Rule 8
Matchmaker Pontic Fill	5052674MET-CERAM4T	16187	Rule 8
Matchmaker MC Porcelain	5052674MET-CERAM4T	16187	Rule 8
Matchmaker MC Powders	5052674MET-CERAM4T	16187	Rule 8
Matchmate Alloy NP20	5052674BOND-ALLOYGJ	35857	Rule 8
Natura Teeth	5052674TEETH-CL2ASR	38643	Rule 5
Pegasus Pourable Cold Cure Denture Base	5052674CC-DENT-BASEUG	63591	Rule 5
Pegasus Plus Denture Base	5052674DENTBASE-REPAIR7Q	63591	Rule 5
Pegasus Plus Repair Acrylic	5052674DENTBASE-REPAIR7Q	63591	Rule 5
Propaque Instant Opaque	5052674MET-CERAM4T	16187	Rule 5
Quicktemp 2	5052674TEMP-CROWN23	45236	Rule 8
Quicktemp Cosmetic	5052674COMP-FILL68	45236	Rule 8
Quicktemp Cosmetic Glaze and Bond	5052674G/B-TEMP-CROWNDD	34771	Rule 5
Schottlander Ultrafine Glass Composite	5052674COMP-FILL68	35870	Rule 8

Title	QC14- Declaration of Conformity	Doc Ref	QC14	Doc Rev no.	7	Date Issued	31/01/2024
-------	--	---------	-------------	-------------	----------	-------------	-------------------

The management system of Schottlander further conforms to:

ISO 13485:2016	CERT: GB97/9550ISO
ISO 9001:2015	CERT: GB04/6319
DIRECTIVE 93/42/EEC	CERT GB19/964610
MDSAP ISO 13485:2016	GB20/965704
UKCA	GB23/00000313

Signature:	
Print Name:	Sumitava Dutta
Position:	Systems and Regulatory Affairs Manager
Date:	31.01.2024
Supersedes:	31.03.2023