

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	GMDN Code	Rule
4natur Teeth	38643	Rule 8
Croform Excel S1 Alloy	35857	Rule 5
Delphic Tooth coloured Acrylic	63591	Rule 8
Enigma High Base Denture base	63591	Rule 5
Engima Teeth	38643	Rule 5
Enigmalive Teeth	38643	Rule 5
Matchmate Alloy NP10	35857	Rule 8
Matchmate Alloy NP20	35857	Rule 8
Natura Teeth	38643	Rule 5
Opus PCF Polycarboxylate	16705	Rule 8
Opus Silver	16704	Rule 8
Opuscem GI Luting Cement	16704	Rule 8
Opusfil	16704	Rule 8
Pegasus Cold Cure Pourable Acrylic	63591	Rule 5
Pegasus Plus Denture Base	63591	Rule 5
Pegasus Plus Repair Acrylic	63591	Rule 5
Propaque Paste Opaque	16187	Rule 8
Quicktemp 2	45236	Rule 8
Quicktemp Cosmetic	45236	Rule 8
Quicktemp Cosmetic Flowable Composite	35870	Rule 8
Quicktemp Cosmetic Glaze and Bond	34771	Rule 5
Schottlander Ultrafine Glass Composite	35870	Rule 8
Starburst 45 Amalgam	16367	Rule 8

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

Signature:	
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Position:	QA RA Manager
Date:	1 st December 2021
Supersedes:	6 th October 2021