3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

EC DECLARATION OF CONFORMITY

93/42/EEC on Medical Devices (MDD) as amended by 2007/47/EC

Legal Manufacturer:
3M ESPE Dental Products
2510 Conway Avenue
St. Paul, Minnesota 55144-1000
USA

EN ISO 13485:2016 Certificate
Certificate No: Q5 045735 0041
Valid until: 2025-05-08

Product Family:	Dental Impressioning Systems	Product:	Sof-Lex™ Contouring and Polishing Discs Sof-Lex™ Finishing and Polishing Discs Sof-Lex™ Finishing and Polishing Strips Sof-Lex™ Extra Thin Contouring and Polishing Discs Sof-Lex™ Finishing and Polishing Discs Extra Thin Sof-Lex™ Finishing and Polishing Systems Sof-Lex™ Mandrels
Device Class:	I per Rule V in Annex IX of 93/42/EEC as amended by 2007/47/EC		

Declaration of Conformity

3M ESPE Dental Products has sole responsibility and declares that the CE marked device(s) in this declaration fulfills the relevant provisions of the EC Council Directive 93/42/EEC, as amended by 2007/47/EC, on the approximation of the laws of the European Union Member States concerning medical devices and are in accordance with EN ISO 13485:2016, Medical devices - Quality management systems – Requirements for regulatory purpose.

This declaration is made on the basis of the EN ISO 13485:2016 certificate which has been delivered by TüV SüD Product Service GMBH, Ridlerstrasse 65, 80339 Munich Germany.

3M ESPE Dental Products has appointed 3M Deutschland GmbH as our EU Authorized Representative.

3M Deutschland GmbH
Carl-Schurz-Strasse 1
41453 Neuss, Germany

Suzanne Leung, PhD., RAC
Regulatory Affairs Director
3M ESPE Dental Products

13Oct2022
Date

EC DECLARATION OF CONFORMITY

Western Europe

Item Number	Description
Sof-Lex™ Contouring and Polishing Discs	
Kit	
1980	Sof-Lex Contouring and Polishing Disc Kit • 30 – 1/2 inch (12,7mm) Discs – Coarse • 30 – 1/2 inch (12,7mm) Discs – Medium • 30 – 1/2 inch (12,7mm) Discs – Fine • 30 – 1/2 inch (12,7mm) Discs – Super Fine • 30 – 3/8 inch (9,5mm) Discs – Coarse • 30 – 3/8 inch (9,5mm) Discs – Medium • 30 – 3/8 inch (9,5mm) Discs – Fine • 30 – 3/8 inch (9,5mm) Discs – Super Fine • 1 – RA Mandrel • Instructions for Use – Mandrel and Discs
Refills	
1981C	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Coarse
1981M	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Medium
1981F	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Fine
1981SF	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs – Super Fine
1982C	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Coarse
1982M	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Medium
1982F	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Fine
1982SF	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs – Super Fine
Sof-Lex™ Extra Thin Contouring and Polishing Discs	
Kit	
2380	Sof-Lex Extra Thin Contouring and Polishing Disc Kit • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Coarse • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Medium • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Fine • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Super Fine • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Coarse • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Medium • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Fine • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Super Fine • 1 – RA Mandrel • Instructions for Use – Mandrel and Discs
Refills	
2381C	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Coarse
2381M	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Medium
2381F	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Fine
2381SF	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs – Super Fine

2382C	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Coarse
2382M	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Medium
2382F	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Fine
2382SF	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs – Super Fine
Sof-Lex™ Finishing and Polishing System - Kits	
2385P	Sof-Lex Finishing and Polishing Systems Kit • 30 – 1/2 inch (12,7mm) Discs – Coarse • 30 – 1/2 inch (12,7mm) Discs – Medium • 30 – 1/2 inch (12,7mm) Discs – Fine • 30 – 1/2 inch (12,7mm) Discs – Super Fine • 30 – 3/8 inch (9,5mm) Discs – Coarse • 30 – 3/8 inch (9,5mm) Discs – Medium • 30 – 3/8 inch (9,5mm) Discs – Fine • 30 – 3/8 inch (9,5mm) Discs – Super Fine • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Coarse • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Medium • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Fine • 30 – 1/2 inch (12,7mm) Extra Thin Discs – Super Fine • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Coarse • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Medium • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Fine • 30 – 3/8 inch (9,5mm) Extra Thin Discs – Super Fine • 15 – 7 inches x 5/32 inch (178mm x 4mm) Strips – Coarse/Medium • 15 – 7 inches x 5/64 inch (178mm x 2mm) Narrow Strips – Coarse/Medium • 15 – 7 inches x 5/32 inch (178mm x 4mm) Strips – Fine/Super Fine • 1 – RA Mandrel • Instructions for Use - Mandrel, Discs, and Strips
Sof-Lex™ Finishing and Polishing Discs - Refills	
1958C	Sof-Lex Finishing and Polishing Discs/Coarse 100 – 5/8 inch Square Eyelet Discs - Coarse
1958M	Sof-Lex Finishing and Polishing Discs/Medium 100 – 5/8 inch Square Eyelet Discs - Medium
1958F	Sof-Lex Sof-Lex Finishing and Polishing Discs/Fine 100 – 5/8 inch Square Eyelet Discs - Fine
1958SF	Sof-Lex Sof-Lex Finishing and Polishing Discs/Super Fine 100 – 5/8 inch Square Eyelet Discs – Super Fine
Sof-Lex™ Finishing and Polishing Strips - Refills	
1954	150 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing Strips – Coarse/Medium
1954N	100 – 7 inches x 5/64 inch (178mm x 2mm) Sof-Lex Finishing Strips – Coarse/Medium, Narrow
1956	120 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Polishing Strips – Fine/Super Fine
Sof-Lex™ Mandrels - Refills	
1983RA	3 – RA Mandrels
1983HP	3 – HP Mandrels
1983FG	3 – FG Mandrels
Eastern Europe	
Sof-Lex™ Finishing and Polishing Discs - Refills	

8690C	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Coarse
8690M	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Medium
8690F	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Fine
8690SF	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Super Fine
8691C	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Coarse
8691M	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Medium
8691F	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Fine
8691SF	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Super Fine
Sof-Lex™ Finishing and Polishing Discs Extra Thin - Refills	
8693C	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs - Extra Thin/Coarse
8693M	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Medium
8693F	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Fine
8693SF	50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Super Fine
8692C	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Coarse
8692M	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Medium
8692F	50 – 1/2 inch (12,7mm Sof-Lex Finishing and Polishing Discs Extra Thin/Fine
8692SF	50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Super Fine
Sof-Lex™ Contouring and Polishing Discs - Kit	
1980	Sof-Lex Contouring and Polishing Discs • 30 – 1/2 inch (12,7mm) Discs Standard /Coarse • 30 – 1/2 inch (12,7mm) Discs Standard /Medium • 30 – 1/2 inch (12,7mm) Disc Standard s/Fine • 30 – 1/2 inch (12,7mm) Discs Standard /Super Fine • 30 – 3/8 inch (9,5mm) Discs Standard /Coarse • 30 – 3/8 inch (9,5mm) Discs Standard /Medium • 30 – 3/8 inch (9,5mm) Discs Standard /Fine • 30 – 3/8 inch (9,5mm) Discs Standard /Super Fine • 1 – Mandrel • Instructions for Use – Mandrel and Discs
Sof-Lex™ Extra Thin Contouring and Polishing Discs - Kit	
2380	Sof-Lex Extra Thin Contouring and Polishing Discs • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Coarse • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Medium • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Fine • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Super Fine • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Coarse • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Medium • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Fine • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Super Fine • 1 – Mandrel • Instructions for Use – Mandrel and Discs
Sof-Lex™ Finishing and Polishing System - Kit	

2385P		Sof-Lex Finishing and Polishing Systems Kit • 30 – 1/2 inch (12,7mm) Discs Standard/Coarse • 30 – 1/2 inch (12,7mm) Discs Standard /Medium • 30 – 1/2 inch (12,7mm) Discs Standard /Fine • 30 – 1/2 inch (12,7mm) Discs Standard /Super Fine • 30 – 3/8 inch (9,5mm) Discs Standard /Coarse • 30 – 3/8 inch (9,5mm) Discs Standard /Medium • 30 – 3/8 inch (9,5mm) Discs Standard /Fine • 30 – 3/8 inch (9,5mm) Discs Standard /Super Fine • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Coarse • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Medium • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Fine • 30 – 1/2 inch (12,7mm) Discs Extra Thin/Super Fine • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Coarse • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Medium • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Fine • 30 – 3/8 inch (9,5mm) Discs Extra Thin/Super Fine • 15 – 7 inches x 5/32 inch (178mm x 4mm) Strips – Coarse/Medium • 15 – 7 inches x 5/64 inch (178mm x 2mm) Narrow Strips – Coarse/Medium • 15 – 7 inches x 5/32 inch (178mm x 4mm) Strips – Fine/Super Fine • 1 – Mandrel • Instructions for Use - Mandrel, Discs, and Strips
Sof-Lex™ Finishing and Polishing Strips - Refills		
1954		150 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing Strips – Coarse/Medium
1954N		100 – 7 inches x 5/64 inch (178mm x 2mm) Sof-Lex Finishing Strips – Coarse/Medium, Narrow
1956		120 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Polishing Strips – Fine/Super Fine
Sof-Lex™ Mandrels - Refill		
8695CA		2 – CA Mandrels