3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144 USA

EC DECLARATION OF CONFORMITY

Annex VII of Council Directive 93/42/EEC concerning Medical Devices.

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

ISO Certificate No: Q5 045735 0036
Valid until: 2022-05-08

GMDN CODE 35702 – Abrasive strips, dental
35170 – Mandrel, dental
64617—Dental abrasive disk, single-use

Manufacturing Facility:
3M ESPE Dental Products
2111 McGaw Avenue
Irvine, California 92614
USA

Product Family: Abrasives

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

EC Product Class: I
Rule: 5 Per Annex IX of the Medical Device Directive

Declaration of Conformity

3M ESPE Dental Products has sole responsibility and declares that devices on the attached Device Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and is in accordance with ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes, as implemented by the European Union's Medical Devices Regulations.

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	Manager 3M ESPE Regulatory Affairs	St. Paul, MN USA	13 Dec 2019
Suzanne Leung	Title	Location	Date

EC DECLARATION OF CONFORMITY

Product Family:	Abrasives
Device Description:	See below
EC Product Class (Per Annex IX Rules):	Class: I Rule: 5 of Annex IX of the Medical Device Directive
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

Western Europe	
Item	**Catalogue/Order Number**
Sof-Lex™ Contouring and Polishing Discs	
Kit	
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	1980
Refills	
85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Coarse	1981C
85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Medium	1981M
85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Fine	1981F
85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs – Super Fine	1981SF
85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Coarse	1982C
85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Medium	1982M
85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Fine	1982F
85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs – Super Fine	1982SF
Sof-Lex™ Extra Thin Contouring and Polishing Discs	
Kit	
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	2380

Refills	
85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Coarse	2381C
85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Medium	2381M
85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Fine	2381F
85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin Contouring and Polishing Discs – Super Fine	2381SF
85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Coarse	2382C
85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Medium	2382M
85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs - Fine	2382F
85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin Contouring and Polishing Discs – Super Fine	2382SF
Sof-Lex™ Finishing and Polishing System - Kits	
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	2385P
Sof-Lex™ Finishing and Polishing Discs - Refills	
Sof-Lex Finishing and Polishing Discs/Coarse 100 – 5/8 inch Square Eyelet Discs - Coarse	1958C
Sof-Lex Finishing and Polishing Discs/Medium 100 – 5/8 inch Square Eyelet Discs - Medium	1958M
Sof-Lex Sof-Lex Finishing and Polishing Discs/Fine 100 – 5/8 inch Square Eyelet Discs - Fine	1958F
Sof-Lex Sof-Lex Finishing and Polishing Discs/Super Fine 100 – 5/8 inch Square Eyelet Discs – Super Fine	1958SF
Sof-Lex™ Finishing and Polishing Strips - Refills	
150 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing Strips – Coarse/Medium	1954
100 – 7 inches x 5/64 inch (178mm x 2mm) Sof-Lex Finishing Strips – Coarse/Medium, Narrow	1954N
120 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Polishing Strips – Fine/Super Fine	1956

Sof-Lex™ Mandrels - Refills	
3 – RA Mandrels	1983RA
3 – HP Mandrels	1983HP
3 – FG Mandrels	1983FG

Eastern Europe	
Item	**Catalogue/Order Number**
Sof-Lex™ Finishing and Polishing Discs - Refills	
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Coarse	8690C
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Medium	8690M
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Fine	8690F
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs- Standard/Super Fine	8690SF
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Coarse	8691C
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Medium	8691M
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Fine	8691F
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs- Standard/Super Fine	8691SF
Sof-Lex™ Finishing and Polishing Discs Extra Thin - Refills	
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs - Extra Thin/Coarse	8693C
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Medium	8693M
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Fine	8693F
50 – 3/8 inch (9,5mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Super Fine	8693SF
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Coarse	8692C
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Medium	8692M
50 – 1/2 inch (12,7mm Sof-Lex Finishing and Polishing Discs Extra Thin/Fine	8692F
50 – 1/2 inch (12,7mm) Sof-Lex Finishing and Polishing Discs Extra Thin/Super Fine	8692SF
Sof-Lex™ Contouring and Polishing Discs - Kit	
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	1980

Sof-Lex™ Extra Thin Contouring and Polishing Discs - Kit	
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	2380
Sof-Lex™ Finishing and Polishing System - Kit	
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	2385P
Sof-Lex™ Finishing and Polishing Strips - Refills	
150 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing Strips – Coarse/Medium	1954
100 – 7 inches x 5/64 inch (178mm x 2mm) Sof-Lex Finishing Strips – Coarse/Medium, Narrow	1954N
120 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Polishing Strips – Fine/Super Fine	1956
Sof-Lex™ Mandrels - Refill	
2 – CA Mandrels	8695CA