



EC DECLARATION OF CONFORMITY

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

Manufacturer:

3M ESPE Dental Products
3M Center, Bldg. 260
St. Paul, Minnesota 55144-1000
USA

ISO Certificate No: G1 11 11 45735 020
Valid until: 2016-12-03

GMDN CODE 35807 – Discs, dental abrasive
35702 – Abrasive strips, dental
35170 – Mandrel, dental

UMDNS CODE 16-201 – Polishing System
11-282 – Grinding wheel, dental

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 Systems
- Sof-Lex™ Mandrels

CE Mark Date: August 1994

EC Product Class: I
Rule:

Per Annex IX of the Medical Device Directive

Declaration of Conformity

3M ESPE Dental Products 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 13485:2003, 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



Director - 3M ESPE
Regulatory Affairs

Title

St. Paul, Minnesota USA

Location

20 January 2012

Date

EC DECLARATION OF CONFORMITY

Product Family:

Device Description:

EC Product Class (Per Annex IX Rules):

Abrasives

See below

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

- 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 Systems
- Sof-Lex™ Mandrels

Product:

Western Europe	
Catalog/ Order Number	Description
	Sof-Lex™ Contouring and Polishing Discs
1980	Sof-Lex Contouring and Polishing Disc Kit <ul style="list-style-type: none"> • 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
1981 C	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Coarse
1981 M	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Medium
1981 F	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Fine
1981 SF	85 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs – Super Fine
1982 C	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Coarse
1982 M	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Medium
1982 F	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Fine
1982 SF	85 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs – Super Fine
1981 GE	Sof-Lex Studentenset (German Version)
	Sof-Lex™ Finishing and Polishing Discs
1958 C	100 – 5/8 inch Square Eyelet Discs - Coarse
1958 M	100 – 5/8 inch Square Eyelet Discs - Medium
1958 F	100 – 5/8 inch Square Eyelet Discs - Fine
1958 SF	100 – 5/8 inch Square Eyelet Discs – Super Fine
	Sof-Lex™ Finishing and Polishing Strips
1956	120 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing and Polishing Strips – Fine/Super Fine
1954	150 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing and Polishing Strips – Coarse/Medium
1954 N	100 - 7 inches x 5/64 inch (178mm x 2mm) Sof-Lex Finishing and Polishing Strips – Coarse/Medium, Narrow

	Sof-Lex™ Extra Thin Contouring and Polishing Discs
2380	<p>Sof-Lex Extra Thin (XT) Contouring and Polishing Disc Kit</p> <ul style="list-style-type: none"> • 30 – 1/2 inch (12,7mm) XT Discs – Coarse • 30 – 1/2 inch (12,7mm) XT Discs – Medium • 30 – 1/2 inch (12,7mm) XT Discs – Fine • 30 – 1/2 inch (12,7mm) XT Discs – Super Fine • 30 – 3/8 inch (9,5mm) XT Discs – Coarse • 30 – 3/8 inch (9,5mm) XT Discs – Medium • 30 – 3/8 inch (9,5mm) XT Discs – Fine • 30 – 3/8 inch (9,5mm) XT Discs – Super Fine • 1 – RA Mandrel
2381 C	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Coarse
2381 M	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Medium
2381 F	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Fine
2381 SF	85 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs – Super Fine
2382 C	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Coarse
2382 M	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Medium
2382 F	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Fine
2382 SF	85 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs – Super Fine
	Sof-Lex™ Finishing and Polishing Systems Kit
2385 P	<p>Sof-Lex Finishing and Polishing Systems Kit</p> <ul style="list-style-type: none"> • 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) XT Discs – Coarse • 30 – 1/2 inch (12,7mm) XT Discs – Medium • 30 – 1/2 inch (12,7mm) XT Discs – Fine • 30 – 1/2 inch (12,7mm) XT Discs – Super Fine • 30 – 3/8 inch (9,5mm) XT Discs – Coarse • 30 – 3/8 inch (9,5mm) XT Discs – Medium • 30 – 3/8 inch (9,5mm) XT Discs – Fine • 30 – 3/8 inch (9,5mm) XT 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
2385 MP	<p>Sof-Lex Finishing and Polishing System Sample Kit</p> <ul style="list-style-type: none"> • 1- Sof-Lex Polishing Strips - Fine/Superfine • 1- Sof-Lex Polishing Strips - Coarse/Medium, Narrow • 1- Sof-Lex Polishing Strips - Coarse/Medium
2385 GE	Sof-Lex Mustertute (German Version)
2385 ST	Sof-Lex Set Heidelberg (German Version)

	Sof-Lex™ Mandrels
1983 RA	Sof-Lex RA Mandrels (3)
1983 HP	Sof-Lex HP Mandrels (3)
1983 FG	Sof-Lex FG Mandrels (3)
	Eastern Europe
Catalog/ Order Number	Description
	Sof-Lex™ Contouring and Polishing Discs
8691C	50 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Coarse
8691F	50 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Medium
8691M	50 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs - Fine
8691SF	50 – 1/2 inch (12,7mm) Sof-Lex Contouring and Polishing Discs – Super Fine
8690C	50 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Coarse
8690M	50 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Medium
8690F	50 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs - Fine
8690SF	50 – 3/8 inch (9,5mm) Sof-Lex Contouring and Polishing Discs – Super Fine
	Sof-Lex™ Extra Thin Contouring and Polishing Discs
8692C	50 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Coarse
8692M	50 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Medium
8692F	50 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Fine
8692SF	50 – 1/2 inch (12,7mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs – Super Fine
8693C	50 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Coarse
8693F	50 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Medium
8693M	50 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs - Fine
8693SF	50 – 3/8 inch (9,5mm) Sof-Lex Extra Thin (XT) Contouring and Polishing Discs – Super Fine
	Sof-Lex™ Mandrels
8695CA	2 – CA Mandrels
	Sof-Lex™ Finishing and Polishing Strips
1954	150 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing and Polishing Strips – Coarse/Medium
1954N	100 - 7 inches x 5/64 inch (178mm x 2mm) Sof-Lex Finishing and Polishing Strips – Coarse/Medium, Narrow
1956	120 – 7 inches x 5/32 inch (178mm x 4mm) Sof-Lex Finishing and Polishing Strips – Fine/Super Fine

	Sof-Lex™ Contouring and Polishing Discs Kits
1980	<p>Sof-Lex Contouring and Polishing Disc Kit</p> <ul style="list-style-type: none"> • 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 – Mandrel
2380	<p>Sof-Lex Extra Thin (XT) Contouring and Polishing Disc Kit</p> <ul style="list-style-type: none"> • 30 – 1/2 inch (12,7mm) XT Discs – Coarse • 30 – 1/2 inch (12,7mm) XT Discs – Medium • 30 – 1/2 inch (12,7mm) XT Discs – Fine • 30 – 1/2 inch (12,7mm) XT Discs – Super Fine • 30 – 3/8 inch (9,5mm) XT Discs – Coarse • 30 – 3/8 inch (9,5mm) XT Discs – Medium • 30 – 3/8 inch (9,5mm) XT Discs – Fine • 30 – 3/8 inch (9,5mm) XT Discs – Super Fine • 1 – Mandrel
2385P	<p>Sof-Lex Finishing and Polishing Systems Kit</p> <ul style="list-style-type: none"> • 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) XT Discs – Coarse • 30 – 1/2 inch (12,7mm) XT Discs – Medium • 30 – 1/2 inch (12,7mm) XT Discs – Fine • 30 – 1/2 inch (12,7mm) XT Discs – Super Fine • 30 – 3/8 inch (9,5mm) XT Discs – Coarse • 30 – 3/8 inch (9,5mm) XT Discs – Medium • 30 – 3/8 inch (9,5mm) XT Discs – Fine • 30 – 3/8 inch (9,5mm) XT 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 – Mandrel