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: Q1N 17 02 45735 033
Valid until: 2020-03-09

GMDN CODE 35807 – Discs, dental abrasive
35170 – Mandrel, dental

UMDNS CODE 11-282 – Disks, dental

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

Product Family: Abrasive

Product:
- Sof-Lex™ Diamond Polishing System
- Sof-Lex™ Pre-Polishing Spiral
- Sof-Lex™ Diamond Polishing Spiral

CE Mark Date: June 2015

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 13485:2003, 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

Gretchen E. Keenan	Manager 3M ESPE Regulatory Affairs	St. Paul, MN USA	30 Mar 2017
Gretchen E. Keenan	Title	Location	Date

EC DECLARATION OF CONFORMITY

Product Family: Abrasive
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™ Diamond Polishing System
- Sof-Lex™ Pre-Polishing Spiral
- Sof-Lex™ Diamond Polishing Spiral

Item	Catalogue/Order Number
Kits	
Sof-Lex Diamond Polishing System • 5 Pre-Polishing Spiral (Beige) • 5 Diamond Polishing Spiral (Pink) • Instruction for Use	5092-I
Sof-Lex Diamond Polishing System • 5 Pre-Polishing Spiral (Beige) • 5 Diamond Polishing Spiral (Pink) • 1 Mandrel • Instructions for Use	5092-IM
Sof-Lex Diamond Polishing System • 3 Pre-Polishing Spiral (Beige) • 3 Diamond Polishing Spiral (Pink) • Instruction for Use	5092-S
Sof-Lex Diamond Polishing System • 3 Pre-Polishing Spiral (Beige) • 3 Diamond Polishing Spiral (Pink) • 1 Mandrel • Instructions for Use	5092-SM
Refills	
Sof-Lex Pre-Polishing Spiral • 15 Pre-Polishing Spiral (Beige) • Instruction for Use	5090
Sof-Lex Diamond Polishing Spiral • 15 Diamond Polishing Spiral (Pink) • Instruction for Use	5091