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

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