



**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

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**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

Manager  
3M ESPE  
Regulatory Affairs  
Title

St. Paul, MN USA  
Location

30 Mar 2017  
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  
 ♦ Sof-Lex™ Diamond Polishing System  
 ♦ Sof-Lex™ Pre-Polishing Spiral  
 ♦ Sof-Lex™ Diamond Polishing Spiral  
**Product:**

Item	Catalogue/Order Number
<b>Kits</b>	
<b>Sof-Lex Diamond Polishing System</b> <ul style="list-style-type: none"> <li>• 5 Pre-Polishing Spiral (Beige)</li> <li>• 5 Diamond Polishing Spiral (Pink)</li> <li>• Instruction for Use</li> </ul>	5092-I
<b>Sof-Lex Diamond Polishing System</b> <ul style="list-style-type: none"> <li>• 5 Pre-Polishing Spiral (Beige)</li> <li>• 5 Diamond Polishing Spiral (Pink)</li> <li>• 1 Mandrel</li> <li>• Instructions for Use</li> </ul>	5092-IM
<b>Sof-Lex Diamond Polishing System</b> <ul style="list-style-type: none"> <li>• 3 Pre-Polishing Spiral (Beige)</li> <li>• 3 Diamond Polishing Spiral (Pink)</li> <li>• Instruction for Use</li> </ul>	5092-S
<b>Sof-Lex Diamond Polishing System</b> <ul style="list-style-type: none"> <li>• 3 Pre-Polishing Spiral (Beige)</li> <li>• 3 Diamond Polishing Spiral (Pink)</li> <li>• 1 Mandrel</li> <li>• Instructions for Use</li> </ul>	5092-SM
<b>Refills</b>	
<b>Sof-Lex Pre-Polishing Spiral</b> <ul style="list-style-type: none"> <li>• 15 Pre-Polishing Spiral (Beige)</li> <li>• Instruction for Use</li> </ul>	5090
<b>Sof-Lex Diamond Polishing Spiral</b> <ul style="list-style-type: none"> <li>• 15 Diamond Polishing Spiral (Pink)</li> <li>• Instruction for Use</li> </ul>	5091