

3M ESPE  
Dental Products

3M Center, Bldg 260-2A-11  
St. Paul, MN 55144 USA



## EC DECLARATION OF CONFIRMITY

Annex II, Clause 3 of Council Directive 93/42/EEC concerning Medical Devices

### Manufacturer:

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

EC Certificate No: G1 11 11 45735 020

Valid until: 2020-12-03

GMDN CODE: 35875

UMDNS CODE: 17-619

### Manufacturing Facility:

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

Product Family: Polishing and finishing  
Materials

Product: Sof-Lex Finishing and  
Polishing Discs

CE Mark Date: Sept. 23, 2014

EC Product Class: I

Rule: 5

Per Annex IX of the Medical Device Directive

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### Declaration of conformity

3MESPE Dental Products declares that devices listed on the attached Device Schedule conform to the relevant provision of the EC Council Directive 93/42/EEC dated 14 June 1993 and are 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 and verified by TuV SuD Product Service GMBH, CE 0123.

A handwritten signature in blue ink, appearing to read 'John Keenan', is written over a horizontal line.

Director - 3M ESPE

Regulatory Affairs

St. Paul, Minnesota USA 2 April 2016

Signature

Title

Location

Date

## EC DECLARATION OF CONFORMITY

<b>Product Family:</b>	Polishing and Finishing Materials
<b>Device Description:</b>	Non-Sterile Polishing and Finishing Materials
<b>EC Product Class (Per Annex IX Rules):</b>	Class: I Rule: 5
<b>Product:</b>	Sof-Lex Finishing and Polishing Discs

Item	Catalogue/Order Number
Sof-Lex Finishing and Polishing Discs – Extra Thin/Superfine, 50psc.	8692SF
Sof-Lex Finishing and Polishing Discs – Extra Thin/Superfine, 50psc.	8693SF
Sof-Lex Finishing and Polishing Discs – Extra Thin/Fine, 50psc.	8692F
Sof-Lex Finishing and Polishing Discs – Extra Thin/Fine, 50psc.	8693F
Sof-Lex Finishing and Polishing Discs – Extra Thin/Medium, 50psc.	8692M
Sof-Lex Finishing and Polishing Discs – Extra Thin/Medium, 50psc.	8693M
Sof-Lex Finishing and Polishing Discs – Extra Thin/Coarse, 50psc.	8692C
Sof-Lex Finishing and Polishing Discs – Extra Thin/Coarse, 50psc.	8693C