

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

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.

Director - 3M ESPE
Regulatory Affairs St. Paul, Minnesota USA 2 April 2016

Signature

Title

Location

Date

EC DECLARATION OF CONFORMITY

Product Family: Polishing and Finishing Materials
Device Description: Non-Sterile Polishing and Finishing Materials
EC Product Class (Per Annex IX Rules): Class: I Rule: 5
Product: 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 |