

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: Q5 045735 0036
Valid until: 2022-05-08

GMDN CODE: 35807 – Discs, dental abrasive
35702 – Abrasive strips, dental
35170 – Mandrel, dental

Manufacturing Facility:

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

Product Family: Abrasives

Product: ♦ Sof-Lex™ Spiral Finishing Wheels
♦ Sof-Lex™ Spiral Polishing Wheels
♦ Sof-Lex™ System - Spiral Wheels,
Discs, and Strips

EC Product Class: I
Rule: 5

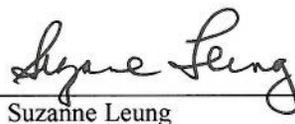
Per Annex IX of the Medical Device Directive

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 13485:2016, 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


Suzanne Leung

Manager
3M ESPE
Regulatory Affairs
Title
St. Paul, MN USA
Location

06 Sep 2019
Date

EC DECLARATION OF CONFORMITY

Product Family: Abrasives
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™ Spiral Finishing Wheels
 ♦ Sof-Lex™ Spiral Polishing Wheels
Product: ♦ Sof-Lex™ System - Spiral Wheels, Discs, and Strips

Item Description	Catalogue/Order Number
Western Europe	
Kits	
Sof-Lex Introductory Kit - Spiral Wheels <ul style="list-style-type: none"> • 10 Spiral Finishing Wheels • 10 Spiral Polishing Wheels • 1 Mandrel • Instructions for Use - Spiral Wheels and Mandrel 	5082I
Sof-Lex Sample Kit - Spiral Wheels <ul style="list-style-type: none"> • 3 Spiral Finishing Wheels • 3 Spiral Polishing Wheels • 1 Mandrel • Instructions for Use - Spiral Wheels and Mandrel 	5082S
Refills	
Sof-Lex Spiral Finishing Wheels <ul style="list-style-type: none"> • 30 Spiral Finishing Wheels • Instructions for Use - Spiral Wheels 	5080
Sof-Lex Spiral Polishing Wheels <ul style="list-style-type: none"> • 30 Spiral Polishing Wheels • Instructions for Use - Spiral Wheels 	5081

Eastern Europe	
Kits	
Sof-Lex Introductory Kit - Spiral Wheels <ul style="list-style-type: none"> • 6 Spiral Finishing Wheels • 6 Spiral Polishing Wheels • 1 Mandrel • Instructions for Use - Spiral Wheels and Mandrel 	5082I
Sof-Lex Sample Kit - Spiral Wheels (with mandrel) <ul style="list-style-type: none"> • 3 Spiral Finishing Wheels • 3 Spiral Polishing Wheels • 1 Mandrel • Instructions for Use - Spiral Wheels and Mandrel 	5082S
Sof-Lex Sample Kit - Spiral Wheels (without mandrel) <ul style="list-style-type: none"> • 3 Spiral Finishing Wheels • 3 Spiral Polishing Wheels • Instructions for Use - Spiral Wheels 	5082S
Refills	
Sof-Lex Spiral Finishing Wheels <ul style="list-style-type: none"> • 12 Spiral Finishing Wheels • Instructions for Use - Spiral Wheels 	5080
Sof-Lex Spiral Polishing Wheels <ul style="list-style-type: none"> • 12 Spiral Polishing Wheels • Instructions for Use - Spiral Wheels 	5081