

**EUROPEAN MEDICAL DEVICE REGULATION****Declaration of Conformity**

As Legal Manufacturer, we

3M ESPE Dental Products

Single Registration Number: US-MF-000030490

2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked device(s)

Trade Name	3M™ Sof-Lex™ Finishing Strips 3M™ Sof-Lex™ Polishing Strips
Intended Purpose	The 3M™ Sof-Lex™ Finishing and Polishing Strips are used to provide contouring, finishing, and polishing to dental restorations.
Reference	1954 1954N (3M™ Sof-Lex™ Finishing Strips) 1956 (3M™ Sof-Lex™ Polishing Strips)
Basic UDI-DI	06082238401020000000008B9

are classified per rule 5 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

EU Authorized Representative:

EU Representative Address

3M Deutschland GmbH

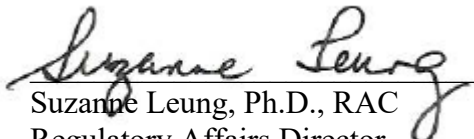
Health Care Business

Single Registration Number:

DE-AR-000012860

Carl-Schurz-Str. 1

41453 Neuss, Germany


Suzanne Leung, Ph.D., RAC
Regulatory Affairs Director
3M Oral Care Solutions Division

17NOV2022 (St. Paul, MN)
Location/Date

3M, ESPE, and Sof-Lex are trademarks of 3M Company or 3M Deutschland GmbH.