

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

As Legal Manufacturer, we

3M ESPE Dental Products
Single Registration Number: *TBD*
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.

The Authorized European Representative for the concerned devices is

3M Deutschland GmbH
Health Care Business
Single Registration Number: TBD
Carl-Schurz-Str. 1
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19 Jan 2021

Date