# *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* | Sof-Lex™ HP Mandrels, 1983HP<br>Sof-Lex™ RA Mandrels, 1983RA<br>Sof-Lex™ Finishing and Polishing Mandrels, 8695CA |
| Intended Purpose | 3M™ Sof-Lex™ Mandrels are intended for use with the 3M™ Sof-Lex™ Diamond Polishing System and 3M™ Sof-Lex™ Finishing and Polishing System. |
| Catalog Number Reference | 1983HP\|1983RA\|8695CA |
| Basic UDI-DI | 06082238401020000000009BB |

is classified per rule 5 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class 1 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 device(s) is

3M Deutschland GmbH
Health Care Business
Single Registration Number*: TBD*
Carl-Schurz-Str. 1
41453 Neuss, Germany

Suzanne Leung

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Suzanne Leung, PhD., RAC
Division Regulatory Affairs Manager
3M ESPE Dental Products
2510 Conway Ave. St. Paul, MN 55144 USA

3 April 2020
Date