

3M ESPE  
Dental Products

2510 Conway Avenue  
St. Paul, MN 55144 USA



## EC DECLARATION OF CONFORMITY

93/42/EEC on Medical Devices (MDD) Annex II excluding (4).

### Manufacturer:

3M ESPE Dental Products  
2510 Conway Avenue  
St. Paul, Minnesota 55144-1000  
USA

EC Certificate No: G1 16 05 45735 030  
Valid until: 2021-12-03

GMDN CODE: 34976 Dental Crown,  
preformed, temporary

### Manufacturing Facility:

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

Product Family: Preformed Crowns

Product: Polycarbonate Crowns

EC Product Class: IIa  
Rule: 8

Per Annex IX of the Medical Device Directive

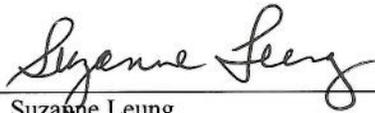
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## Declaration of Conformity

3M ESPE Dental Products has sole responsibility and declares that the devices listed on the attached Device Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and are 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 and verified by TÜV SÜD Product Service GMBH, Ridlerstrasse 65, 80339 Munich Germany, CE 0123.

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:**

**Device Description:**

**EC Product Class (Per Annex IX Rules):**

**Product:**

**Preformed Crowns**

Non-Sterile Dental Crown

Class: IIa Rule: 8

◆ Polycarbonate Crowns

| Item Number            | Description   |    |    |    |    |     |     |
|------------------------|---|----|----|----|----|-----|-----|
| <b>Kits</b>            |   |    |    |    |    |     |     |
| C-180                  | Adult Anterior Set<br>◆ 180 Crowns <ul style="list-style-type: none"> <li>• 120 individual crowns</li> <li>• 60 crowns attached to 10 Mold Guides</li> </ul> ◆ Instructions |    |    |    |    |     |     |
| <b>Refills</b>         | <b>Adult Anterior Crown Replacements – 5 crowns per box</b>   |    |    |    |    |     |     |
| Upper Left Centrals    | 15  | 16 | 17 | 18 | 19 | 102 | 103 |
| Upper Left Laterals    | 25  | 26 | 27 | 28 | 29 | 200 |     |
| Upper Left Cuspids     | 35  | 36 | 37 | 38 | 39 | 302 | 303 |
| Upper Right Centrals   | 10  | 11 | 12 | 13 | 14 | 100 | 101 |
| Upper Right Laterals   | 20  | 21 | 22 | 23 | 24 | 2   |     |
| Upper Right Cuspids    | 30  | 31 | 32 | 33 | 34 | 300 | 301 |
| Bicuspids (First)      | 40  | 41 | 42 | 43 | 44 |     |     |
| Bicuspids (Second)     | 50  | 51 | 52 | 53 | 54 |     |     |
| Lower Incisors (Long)  | 60  | 61 | 62 | 63 | 64 |     |     |
| Lower Incisors (Short) | 65  | 66 | 67 | 68 | 69 |     |     |