

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: Iso-Form™ Crowns

EC Product Class: IIa
Rule: 8

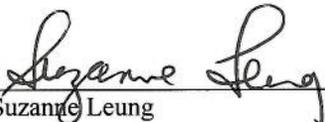
Per Annex IX of the Medical Device Directive

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: Preformed Crowns
Device Description: Dental Crowns
EC Product Class (Per Annex IX Rules): Class: IIa Rule: 8
Product: ♦ Iso-Form™ Crowns

Product Code	Product Name/Descriptor			
Kits				
MC 64	Molar Set ♦ 64 Crowns ♦ Measuring Gage ♦ Stretch Block ♦ Instructions			
BC 64	Bicuspid Set ♦ 64 Crowns ♦ Measuring Gage ♦ Stretch Block ♦ Instructions			
Refills	5 Crowns of one size per box			
	First Bicuspid	First Bicuspid	First Molar	Second Molar
Upper Right	U-40	U-50	U-60	U-70
	U-42	U-52	U-62	U-72
	U-44	U-54	U-64	U-74
	U-46	U-56	U-66	U-76
	U-48	U-58	U-68	U-78
Upper Left	U-41	U-51	U-61	U-71
	U-43	U-53	U-63	U-73
	U-45	U-55	U-65	U-75
	U-47	U-57	U-67	U-77
	U-49	U-59	U-69	U-79
Lower Right	L-40	L-50	L-60	L-70
	L-42	L-52	L-62	L-72
	L-44	L-54	L-64	L-74
	L-46	L-56	L-66	L-76
	L-48	L-58	L-68	L-78
Lower Left	L-41	L-51	L-61	L-71
	L-43	L-53	L-63	L-73
	L-45	L-55	L-65	L-75
	L-47	L-57	L-67	L-77
	L-49	L-59	L-69	L-79