



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: Stainless Steel 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

Date

06 Sep 2019

EC DECLARATION OF CONFORMITY

Product Family:	<u>Preformed Crowns</u>
Device Description:	Non-Sterile Dental Crowns
EC Product Class (Per Annex IX Rules):	Class: IIa Rule: 8
Product:	◆ Stainless Steel Crowns

3M™ ESPE™ Stainless Steel Crowns

Product Code	Product Name/Descriptor					
Kits						
ND-96	Primary Molar Set ◆ 96 Crowns ◆ Instructions					
ND-48	Primary Molar Set ◆ 48 Crowns ◆ Instructions					
PO-96	Permanent Molar Set ◆ 96 Crowns ◆ Instructions					
Refills	The Stainless Steel Crown refills are available in two configurations: ➤ 5 Crowns of one size per box (Primary Molar & Permanent Molar) or ➤ 2 Crowns of one size per box (Primary Molar only)					
First Primary Molar Stainless Steel						
Upper Right	DUR2	DUR3	DUR4	DUR5	DUR6	DUR7
Upper Left	DUL2	DUL3	DUL4	DUL5	DUL6	DUL7
Lower Right	DLR2	DLR3	DLR4	DLR5	DLR6	DLR7
Lower Left	DLL2	DLL3	DLL4	DLL5	DLL6	DLL7
Second Primary Molar						
Upper Right	EUR2	EUR3	EUR4	EUR5	EUR6	EUR7
Upper Left	EUL2	EUL3	EUL4	EUL5	EUL6	EUL7
Lower Right	ELR2	ELR3	ELR4	ELR5	ELR6	ELR7
Lower Left	ELL2	ELL3	ELL4	ELL5	ELL6	ELL7
First Permanent Molar						
Upper Right	6UR2	6UR3	6UR4	6UR5	6UR6	6UR7
Upper Left	6UL2	6UL3	6UL4	6UL5	6UL6	6UL7
Lower Right	6LR2	6LR3	6LR4	6LR5	6LR6	6LR7
Lower Left	6LL2	6LL3	6LL4	6LL5	6LL6	6LL7

3M™ ESPE™ Unitek™ Stainless Steel Crowns

Product Code	Product Name/Descriptor							
Kits								
908100	Primary Anterior Crown Set ◆ 72 Crowns ◆ Instructions							
902150	Primary Molar Crown Set ◆ 112 Crowns ◆ Instructions							
902600	Permanent Bicuspid Set ◆ 84 Crowns ◆ Instructions							
902350	Permanent Molar Set ◆ 84 Crowns ◆ Instructions							
Refills	5 Crowns of one size per box (Primary Molar & Permanent Molar)							
Primary Anterior Crown Series								
	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6		
UL Central	907001	907002	907003	907004	907005	907006		
UR Central	907011	907012	907013	907014	907015	907016		
UL Lateral	907021	907022	9070123	907024	907025	907026		
UR Lateral	907031	907032	907033	907034	907035	907036		
Upper Bicuspid	907041	907042	9070343	907044	907045	907046		
Lower Bicuspid	907051	907052	907053	9070354	907055	907056		
First Primary Molar Crown Series								
	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	Size 7	
Upper Left	900111	900112	900113	900114	900115	900116	900117	
Upper Right	900121	900122	900123	900124	900125	900126	900127	
Lower Left	900131	900132	900133	900134	900135	900136	900137	
Lower Right	900141	900142	900143	900144	900145	900146	900147	
Second Primary Molar Crown Series								
	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	Size 7	
Upper Left	900211	900212	900213	900214	900215	900216	900217	
Upper Right	900221	900222	900223	900224	900225	900226	900227	
Lower Left	900231	900232	900233	900234	900235	900236	900237	
Lower Right	900241	900242	900243	900244	900245	900246	900247	
First Permanent Bicuspid Crown Series								
	Size 00	Size 0	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6
Upper Left	900509	900510	900511	900512	900513	900514	900515	900516
Upper Right	900519	900520	900521	900522	900523	900524	900525	900526
Lower Left		900530	900531	900532	900533	900534	900535	900536

Lower Right		900540	900541	900542	900543	900544	900545	900546
Second Permanent Bicuspid Crown Series								
	Size 0	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	
Lower Left	900630	900631	900632	900633	900634	900635	900636	
Lower Right	900640	900641	900642	900643	900644	900645	900646	
First Permanent Molar Crown Series								
	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	Size 7	
Upper Left	900311	900312	900313	900314	900315	900316	900317	
Upper Right	900321	900322	900323	900324	900325	900326	900327	
Lower Left	900331	900332	900333	900334	900335	900336	900337	
Lower Right	900341	900342	900343	900344	900345	900346	900347	
Second Permanent Molar Crown Series								
	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6		
Lower Left	900431	900432	900433	900434	900435	900436		
Lower Right	900441	900442	900443	900444	900445	900446		