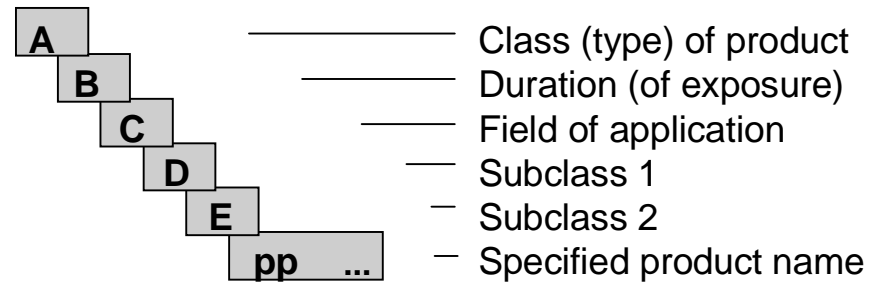


Coding of dental biomaterials as used by the Norwegian Adverse Reaction Unit

Revision 1998
(Draft English version)

Coding of dental biomaterials as used by The Adverse Reaction Unit



A: 1 - "Invasive devices used in the oral cavity (clinical use)"
 2 - "Invasive devices, oral cavity, patient use"
 3 - "Non invasive devices"

B: 1 - "Long term use" (> 30 d)
 2 - "Short term use" (max. 30 d)
 3 - "Transient use" (max. 60 min)

C: 1- - Field of application (E.g. filling materials, cavity lining materials)
 0 - Not evident

D: 1- - Subclass 1 (E.g. Metallic, polymeric filling materials)

E: 1- - Subclass 2 (E.g. Amalgam)

pp.. 1- - Specific product name
 0 - Not given

Based on CEN CR
 12401 "Guidance on
 the classification of
 dental devices and
 accessories"

May 1996

INVASIVE DEVICES USED IN THE ORAL CAVITY (CLINICAL USE)
LONG TERM USE (> 30 d)

EC no.	Material	EC Rule, Class	Sub cl.	Coding		Comments
1	Invasive devices used in the oral cavity (clinical use)					
1.1	Long term use(> 30 d)			1.1.00.0.0		
1.1.1	Plastic materials for direct insertion	8,IIA	0	1.1.01.0.0	110100 000	
	Metals		1	1.1.01.1.0	110110 000	
	Amalgam		2	1.1.01.1.1	110111 ***	
	Other metals		2	1.1.01.1.9	110119 ***	
	Polymers		1	1.1.01.2.0	110120 ***	
	Cements		1	1.1.01.3.0	110130 ***	
	"Compomers"		1	1.1.01.4.0	110140 ***	
1.1.2	Cavity lining materials	8,IIA	0	1.1.02.0.0	110200 ***	
1.1.3	Dentin adhesives	8,IIA	0	1.1.03.0.0	110300 ***	
1.1.4	Pit and fissure sealants	5,IIA	0	1.1.04.0.0	110400 ***	
1.1.5	Protective films (long term)	5,IIA	0	1.1.05.0.0	110500 ***	
1.1.6	Pulp capping		0	1.1.06.0.0	110600 000	
	"Non medicated"	8,IIA	1	1.1.06.1.0	110610 ***	
	"Medicated"	13,III	1	1.1.06.2.0	110620 ***	
1.1.7	Endodontic filling materials	8,IIA	0	1.1.07.0.0	110700 000	
	Sealers		1	1.1.07.1.0	110710 ***	
	Points		1	1.1.07.2.0	110720 ***	
	Retrograde root canal filling materials		1	1.1.07.3.0	110730 ***	
	Metals		2	1.1.07.3.1	110731 ***	
	Polymers		2	1.1.07.3.2	110732 ***	
	Cements		2	1.1.07.3.3	110733 ***	
1.1.8	Luting materials	8,IIA	0	1.1.08.0.0	110800 000	

	Water-based cements		1	1.1.08.1.0	110811 ***	
	Zinc phosphate cements		2	1.1.08.1.1	110811 ***	
	Polyalkenoate cements		2	1.1.08.1.2	110812 ***	
	Resin-based cements		1	1.1.08.2.0	110820 ***	
1.1.9	Materials for fixed prostheses and inlays	8,IIA	0	1.1.09.0.0	110900 000	
	Metals		1	1.1.09.1.0	110910 ***	
	• 50% noble metals		2	1.1.09.1.1	110911 ***	
	< 50% noble metals		2	1.1.09.1.2	110912 ***	
	Non-noble ("Base metals")		2	1.1.09.1.3	110913 ***	
	Polymers		1	1.1.09.2.0	110920 ***	
	Ceramics and glasses		1	1.1.09.3.0	110930 ***	
	Metal-ceramic		1	1.1.09.5.0	110950 ***	
	• 50% noble metals		2	1.1.09.5.1	110951 ***	
	< 50% noble metals		2	1.1.09.5.2	110952 ***	
	Non-noble ("Base metals")		2	1.1.09.5.3	110953 ***	
1.1.10	Materials for removable prostheses	5,IIA	0	1.1.10.0.0	111000 000	
	Metals	(Rule 2.5)	1	1.1.10.1.0	111010 ***	
	• 50% noble metals		2	1.1.10.1.1	111011 ***	
	< 50% noble metals		2	1.1.10.1.2	111012 ***	
	Non-noble ("Base metals")		2	1.1.10.1.3	111013 ***	
	Polymers		1	1.1.10.2.0	111020 ***	
	Ceramics		1	1.1.10.3.0	111030 ***	
1.1.11	Orthodontic materials/devices, intraoral use	5,IIA	0	1.1.11.0.0	111100 000	
	Metals		1	1.1.11.1.0	111110 ***	
	Polymers		1	1.1.11.2.0	111120 ***	
	Ceramic		1	1.1.11.3.0	111130 ***	
1.1.12	Maxillo-facial materials	5,6,IIA	0	1.1.12.0.0	111200 ***	
1.1.13	Dental implants	8,IIB	0	1.1.13.0.0	111300 ***	
	(Several groups. Biologic active 8,III)					
1.1.14	Bone replacement materials		0	1.1.14.0.0	111400 ***	
	Inert	8,IIB	1	1.1.14.1.0	111410 ***	
	Biologic active	8,III	1	1.1.14.2.0	111420 ***	

1.1.15	Materials for guided tissue regeneration		0	1.1.15.0.0	111500 000	
	Inert	8,IIB	1	1.1.15.1.0	111510 ***	
	Biologic active	8,III	1	1.1.15.2.0	111520 ***	
1.1.16	Osteosynthesis materials/devices	8,IIB	0	1.1.16.0.0	111600 ***	

SHORT TERM USE (•30 d)

EC no.	Material	EC Rule, Class	Sub cl.	Coding		Comments
1	Invasive products for use in the oral cavity (clinical use)					
1.2	Short-term use (•30 d)			1.2.00.0.0		
1.2.1	Protective films (varnish)	5,I	0	1.2.01.0.0	120100 ***	
	Protective films (medicated)	13,III	1	1.2.01.1.0	120110 ***	
1.2.2	Temporary filling materials	7,IIA	0	1.2.02.0.0	120200 000	
	Eugenol-containing		1	1.2.02.1.0	120210 ***	
	Non-eugenol		1	1.2.02.2.0	120220 ***	
1.2.3	Temporary crowns and bridges	7,8,IIA	0	1.2.03.0.0	120300 000	
	Prefabricated		1	1.2.03.1.0	120310 ***	
	Materials for custom-made devices		1	1.2.03.2.0	120320 ***	
1.2.4	Short-term lining materials		0	1.2.04.0.0	120400 ***	
	Non medicated	5,I	1	1.2.04.1.0	120410 ***	
	Medicated	13,III	1	1.2.04.2.0	120420 ***	
1.2.5	Surgical dressings	6,IIA	1	1.2.05.1.0	120510 ***	
	Surgical dressings "medicated"	13,III	1	1.2.05.2.0	120520 ***	
1.2.6	Sutures, non-absorbable	6,IIA	1	1.2.06.1.0	120610 ***	
	Sutures, absorbable/medicated	13,III	1	1.2.06.2.0	120620 ***	
1.2.7	Materials for mouthguards	5,I	0	1.2.07.0.0	120700 ***	

1.2.8	Temporary luting/cementing materials	?,IIA	0	1.2.08.0.0	120800 000	
	Eugenol containing		1	1.2.08.1.0	120810 ***	
	Non-eugenol		1	1.2.08.2.0	120820 ***	

TRANSIENT USE (• 60 min)

EC no.	Material	EC Rule, Class	Sub cl.	Coding		Comments
1	Invasive products for use in the oral cavity (clinical use)					
1.3	Transient use (• 60 min)			1.3.00.0.0		
1.3.1	Materials for surface treatment (etching, "primers")	6,IIA	0	1.3.01.0.0	130100 000	
	Cleaning agents, etches		1	1.3.01.1.0	130110 ***	
	Dentin adhesives		1	1.3.01.2.0	130120 ***	
1.3.2	Impression materials	6,IIA	0	1.3.02.0.0	130200 000	
	Hydrocolloids		1	1.3.02.1.0	130210 ***	
	Elastomers		1	1.3.02.2.0	130220 ***	
	Other		1	1.3.02.9.0	130290 ***	
1.3.3	Rubber dam	5,I	0	1.3.03.0.0	130300 ***	
1.3.4	Cotton rolls, pads	5,I	0	1.3.04.0.0	130400 ***	
1.3.5	Dental floss	5,I	0	1.3.05.0.0	130500 ***	
	Dental floss, medicated	13,III	1	1.3.04.1.0	130410 ***	
1.3.6	Wedges	5,I	0	1.3.06.0.0	130600 ***	
	Wedges, medicated	13,III	1	1.3.06.1.0	130610 ***	
1.3.7	Wax	5,I	0	1.3.07.1.0	130700 ***	
1.3.8	Retraction cord	5,I	0	1.3.08.0.0	130800 ***	
	Retraction cord, medicated	13,III	1	1.3.08.1.0	130810 ***	
1.3.9	Matrix bands	5,I	0	1.3.09.0.0	130900 ***	
1.3.10	Impression trays	5,I	0	1.3.10.0.0	131000 ***	
1.3.11	Endodontic absorbent points	6,IIA	0	1.3.11.0.0	131100 ***	
1.3.12	Polishing pastes	5,I	0	1.3.12.0.0	131200 ***	

1.3.13	Polishing strips	5,I	0	1.3.13.0.0	131300 ***	
1.3.14	Materials/devices for articulation and bite registration.	5,I	0	1.3.14.0.0	131400 ***	
1.3.15	X-ray film	16,IIA	0	1.3.15.0.0	131500 ***	
1.3.16*	Gloves	5,I	0	1.3.16.0.0	131600 ***	

2. INVASIVE PRODUCTS, ORAL CAVITY, INTENDED FOR USE IN THE ORAL CAVITY (PATIENT USE)
LONG TERM USE (> 30 d)

EC no.	Material	EC Rule, Class	Sub cl.	Coding		Comments
2	Invasive products for use in the oral cavity (patient use)					
2.1	Long term use (> 30 d)					
2.1.1	Denture adhesives. Soft lining materials.	5,IIA	0	2.1.01.0.0	210100 ***	

SHORT TERM USE (• 30 d)

2.2	Short term use (• 30 d)					
2.2.1	Trays for gels	5,I	0	2.2.01.0.0	220100 ***	
2.2.2	Temporary filling materials	6,IIA	0	2.2.02.0.0	220200 ***	
2.2.3	Bleaching agents (administered by dentist)	(new)		2.2.03.0.0	220300 ***	

TRANSIENT USE (• 60 min) (Repeated exposure)

2.3	Transient use (• 60 min) (Repeated exposure)					
2.3.1	Tooth picks	5,I	0	2.3.01.0.0	230100 ***	
2.3.2	Toothbrushes	5,I	0	2.3.02.0.0	230200 ***	
2.3.3	Mouth rinses	(new)	0	2.3.03.0.0	230300 ***	
2.3.4	Bleaching agents (not administered by dentist)	(new)		2.3.04.0.0	230400 ***	

3. NON-INVASIVE PRODUCTS

EC no.	Material	EC Class	Coding		Comments
3	Non-invasive products				
3.1	Orthodontic materials and devices, extraoral parts.	I	3.1.00.0.0	310000 ***	