



Dental Studio Co., Ltd.

B101, B102, B125, B1, Geumjeong Station 2nd SKV1 Tower, 136 LS-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
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EU DECLARATION OF CONFORMITY

Manufacturer name and address:	Dental Studio Co., Ltd. B101, B102, B125, B1, Geumjeong Station 2nd SKV1 Tower, 136 LS-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
SRN (Single Registration Number):	<i>[Not yet available]</i>
Authorized Representative name and address:	CMC Medical devices & Drugs S.L. C/Horacio Lengo N 18 CP 29006, Málaga-Spain

We, Dental Studio Co., Ltd. hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745.

The device(s) is/are Class 1 following Rule 1 of Annex VIII of REGULATION (EU) 2017/745.
Conformity Assessment Route: Annex IV, EU MDR 2017/745
Notified Body : Not applicable for Class I

The following conformity assessment procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745. and (where relevant) the following CE certificate(s).

The following Standards have been used and in relation to which conformity is declared:

EN ISO 13485[2016], EN ISO 14971[2019], EN 62366-1[2015], EN 1041 [2013], EN ISO 15223-1[2016]

We hereby also declare under our sole responsibility that the device(s) listed in the annex comply(ies) with the provisions of EU Medical Device Regulation 2017/745.

The present declaration is in conformity with Regulation (EU) 2017/745.

Start of CE-marking : June 25, 2021

Issue place and date : Korea, Feb. 10, 2022

Signature



Beom Jun Kim
President of Dental Studio Co., Ltd.

Annex - List of Devices Covered by the Declaration of Conformity

No.	Product name	Model No.	Class	EMDN Code	REGULATION
1.	Needle Holder 14cm	1001	1	Q010599	MDR – Regulation 2017/745
2.	Needle Holder 15cm	1002	1	Q010599	MDR – Regulation 2017/745
3.	Needle Holder 16cm	1003	1	Q010599	MDR – Regulation 2017/745
4.	Mouth Gag 14cm	1051	1	Q010599	MDR – Regulation 2017/745
5.	Needle Holder T/C 14cm	1101	1	Q010599	MDR – Regulation 2017/745
6.	Needle Holder T/C 15cm	1102	1	Q010599	MDR – Regulation 2017/745
7.	Needle Holder T/C 16cm	1103	1	Q010599	MDR – Regulation 2017/745
8.	Needle Holder T/C 18cm	1104	1	Q010599	MDR – Regulation 2017/745
9.	Castroviejo Needle Holder T/C 14cm STR	1105	1	Q010599	MDR – Regulation 2017/745
10.	Castroviejo Needle Holder T/C 14cm CVD	1106	1	Q010599	MDR – Regulation 2017/745
11.	Castroviejo Needle Holder T/C 18cm STR	1107	1	Q010599	MDR – Regulation 2017/745
12.	Castroviejo Needle Holder T/C 18cm CVD	1108	1	Q010599	MDR – Regulation 2017/745
13.	Castroviejo Needle Holder 18cm CVD	1109	1	Q010599	MDR – Regulation 2017/745
14.	Crown Gripper 16cm	1110	1	Q010599	MDR – Regulation 2017/745
15.	CROWN OPENER	1111	1	Q010599	MDR – Regulation 2017/745
16.	Crown Remover CDA	1112	1	Q010599	MDR – Regulation 2017/745
17.	Crown Remover CDB	1113	1	Q010599	MDR – Regulation 2017/745
18.	Crown Remover CR3	1114	1	Q010599	MDR – Regulation 2017/745
19.	HEMOSTATS 14cm	1201	1	Q010599	MDR – Regulation 2017/745
20.	HEMOSTATS 12cm Str	1202	1	Q010599	MDR – Regulation 2017/745
21.	HEMOSTATS 12cm Cvd	1203	1	Q010599	MDR – Regulation 2017/745
22.	HEMOSTATS14cm	1204	1	Q010599	MDR – Regulation 2017/745
23.	Root Splinter Forceps Str	1205	1	Q010599	MDR – Regulation 2017/745
24.	Root Splinter Forceps Cvd	1206	1	Q010599	MDR – Regulation 2017/745
25.	Doubleaction Bone Ronger 18cm	1301	1	Q010599	MDR – Regulation 2017/745



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26.	Bone Ronger 14cm	1303	1	Q010599	MDR – Regulation 2017/745
27.	Towel Clamp	1401	1	Q010599	MDR – Regulation 2017/745
28.	IRIS SCISSOR 11.5cm STR	2001	1	Q010599	MDR – Regulation 2017/745
29.	IRIS SCISSOR 11.5cm CVD	2002	1	Q010599	MDR – Regulation 2017/745
30.	GOLDMAN-FOX SCISSOR 13cm CVD	2004	1	Q010599	MDR – Regulation 2017/745
31.	LAGRANGE SCISSOR 14cm	2005	1	Q010599	MDR – Regulation 2017/745
32.	KELLY SCISSOR 16cm	2006	1	Q010599	MDR – Regulation 2017/745
33.	LOCKLIN SCISSOR 16cm	2007	1	Q010599	MDR – Regulation 2017/745
34.	DEAN SCISSOR 17 cm	2008	1	Q010599	MDR – Regulation 2017/745
35.	CASTROVIEJO SCISSOR 18cm	2009	1	Q010599	MDR – Regulation 2017/745
36.	DEAN SCISSOR 14cm	2011	1	Q010599	MDR – Regulation 2017/745
37.	IRIS SCISSOR T/C 11.5CM STR	2101	1	Q010599	MDR – Regulation 2017/745
38.	IRIS SCISSOR T/C 11.5CM CVD	2102	1	Q010599	MDR – Regulation 2017/745
39.	GOLDMAN-FOX SCISSOR T/C 13CM CVD	2103	1	Q010599	MDR – Regulation 2017/745
40.	KELLY SCISSOR T/C 16cm	2104	1	Q010599	MDR – Regulation 2017/745
41.	DEAN SCISSOR T/C 17cm	2105	1	Q010599	MDR – Regulation 2017/745
42.	Elevator (SAW) 3.5mm Str	3001	1	Q010599	MDR – Regulation 2017/745
43.	Elevator (SAW) 3.0mm Str	3002	1	Q010599	MDR – Regulation 2017/745
44.	Elevator E301 2.3mm Str	3003	1	Q010599	MDR – Regulation 2017/745
45.	Elevator E304W 2.8mm Str	3004	1	Q010599	MDR – Regulation 2017/745
46.	Elevator E81 3.2mm Str	3005	1	Q010599	MDR – Regulation 2017/745
47.	Elevator E41 3.9mm Str	3006	1	Q010599	MDR – Regulation 2017/745
48.	Elevator E34S 4.0mm Str	3007	1	Q010599	MDR – Regulation 2017/745
49.	Elevator E34 5.0mm Str	3008	1	Q010599	MDR – Regulation 2017/745
50.	Elevator E301A 2.5mm Cvd	3009	1	Q010599	MDR – Regulation 2017/745
51.	Elevator E52 3.4mm Cvd	3010	1	Q010599	MDR – Regulation 2017/745
52.	Elevator E73 LIFT	3011	1	Q010599	MDR – Regulation 2017/745
53.	Elevator E74 RIGHT	3012	1	Q010599	MDR – Regulation 2017/745



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54.	Elevator E4 LIFT	3013	1	Q010599	MDR – Regulation 2017/745
55.	Elevator E5 RIGHT	3014	1	Q010599	MDR – Regulation 2017/745
56.	Root Picker STRAIGHT	3015	1	Q010599	MDR – Regulation 2017/745
57.	Root Picker LIFT	3016	1	Q010599	MDR – Regulation 2017/745
58.	Root Picker RIGHT	3017	1	Q010599	MDR – Regulation 2017/745
59.	Root Picker Double	3018	1	Q010599	MDR – Regulation 2017/745
60.	Elevator (Microsaw) 2.5mm Str	3101	1	Q010599	MDR – Regulation 2017/745
61.	Elevator (Microsaw) 2.5mm Cvd	3102	1	Q010599	MDR – Regulation 2017/745
62.	Elevator (Microsaw) 4mm Str	3103	1	Q010599	MDR – Regulation 2017/745
63.	Elevator (Microsaw) 4mm Cvd	3104	1	Q010599	MDR – Regulation 2017/745
64.	Pedodontic FORCEPS 150s	3201	1	Q010599	MDR – Regulation 2017/745
65.	Pedodontic FORCEPS 151s	3202	1	Q010599	MDR – Regulation 2017/745
66.	Tooth Extraction FORCEPS (53R)	3206	1	Q010599	MDR – Regulation 2017/745
67.	Tooth Extraction FORCEPS (53L)	3207	1	Q010599	MDR – Regulation 2017/745
68.	Tooth Extraction FORCEPS (67A)	3208	1	Q010599	MDR – Regulation 2017/745
69.	Tooth Extraction FORCEPS (10S)	3209	1	Q010599	MDR – Regulation 2017/745
70.	Tooth Extraction FORCEPS (150)	3210	1	Q010599	MDR – Regulation 2017/745
71.	Tooth Extraction FORCEPS (17)	3211	1	Q010599	MDR – Regulation 2017/745
72.	Tooth Extraction FORCEPS (222)	3212	1	Q010599	MDR – Regulation 2017/745
73.	Tooth Extraction FORCEPS (151)	3213	1	Q010599	MDR – Regulation 2017/745
74.	Tooth Extraction FORCEPS (1)	3214	1	Q010599	MDR – Regulation 2017/745
75.	Tooth Extraction Root FORCEP (UP)	3215	1	Q010599	MDR – Regulation 2017/745
76.	Tooth Extraction Root FORCEP (Down)	3216	1	Q010599	MDR – Regulation 2017/745
77.	Periotome Incisors	3301	1	Q010599	MDR – Regulation 2017/745
78.	Periotome Molars	3302	1	Q010599	MDR – Regulation 2017/745
79.	Surgical Curettes LUCAS84 2.3mm	4001	1	Q010599	MDR – Regulation 2017/745
80.	Surgical Curettes LUCAS85 2.6mm	4002	1	Q010599	MDR – Regulation 2017/745
81.	Surgical Curettes LUCAS86 2.9mm	4003	1	Q010599	MDR – Regulation 2017/745



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82.	Surgical Curettes LUCAS86-1(SAW) 3.5mm	4004	1	Q010599	MDR – Regulation 2017/745
83.	Surgical Curettes MILLER11 3.5mm	4005	1	Q010599	MDR – Regulation 2017/745
84.	Surgical Curettes MILLER12 4.0mm	4006	1	Q010599	MDR – Regulation 2017/745
85.	Surgical Curettes Molt2/4	4007	1	Q010599	MDR – Regulation 2017/745
86.	Surgical Curettes LUCAS (SAW) 2.5mm	4008	1	Q010599	MDR – Regulation 2017/745
87.	Stopping Stopper 2.6mm	4051	1	Q010599	MDR – Regulation 2017/745
88.	Gracey Curette 1-2	4101	1	Q010599	MDR – Regulation 2017/745
89.	Gracey Curette 3-4	4102	1	Q010599	MDR – Regulation 2017/745
90.	Gracey Curette 5-6	4103	1	Q010599	MDR – Regulation 2017/745
91.	Gracey Curette 7-8	4104	1	Q010599	MDR – Regulation 2017/745
92.	Gracey Curette 9-10	4105	1	Q010599	MDR – Regulation 2017/745
93.	Gracey Curette 11-12	4106	1	Q010599	MDR – Regulation 2017/745
94.	Gracey Curette 13-14	4107	1	Q010599	MDR – Regulation 2017/745
95.	EXCAVATOR 1.5MM	4201	1	Q010599	MDR – Regulation 2017/745
96.	EXCAVATOR 2.0MM	4202	1	Q010599	MDR – Regulation 2017/745
97.	EXCAVATOR 2.5MM	4203	1	Q010599	MDR – Regulation 2017/745
98.	EXCAVATOR 65-66(1.5MM)	4204	1	Q010599	MDR – Regulation 2017/745
99.	Sickle Scaler H5/33	4301	1	Q010599	MDR – Regulation 2017/745
100.	Sickle Scaler J31/32	4302	1	Q010599	MDR – Regulation 2017/745
101.	Sickle Scaler J34/35	4303	1	Q010599	MDR – Regulation 2017/745
102.	Probe cp12	4306	1	Q010599	MDR – Regulation 2017/745
103.	Probe cp15	4307	1	Q010599	MDR – Regulation 2017/745
104.	Probe who	4308	1	Q010599	MDR – Regulation 2017/745
105.	Kirkland Knife	4401	1	Q010599	MDR – Regulation 2017/745
106.	Oban Knife	4402	1	Q010599	MDR – Regulation 2017/745
107.	Bone scraper	4403	1	Q010599	MDR – Regulation 2017/745
108.	Mess Holder Stick	4601	1	Q010599	MDR – Regulation 2017/745
109.	Mess Holder Round STR	4602	1	Q010599	MDR – Regulation 2017/745



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110.	Mess Holder Round CVD	4603	1	Q010599	MDR – Regulation 2017/745
111.	Mess Holder (Moveable)	4604	1	Q010599	MDR – Regulation 2017/745
112.	Periosteal Elevator Molt9	4701	1	Q010599	MDR – Regulation 2017/745
113.	Periosteal Elevator Prichard	4702	1	Q010599	MDR – Regulation 2017/745
114.	Periosteal Elevator Seldin	4703	1	Q010599	MDR – Regulation 2017/745
115.	Periosteal Elevator P24G	4704	1	Q010599	MDR – Regulation 2017/745
116.	Periosteal Elevator 13KT/G	4705	1	Q010599	MDR – Regulation 2017/745
117.	Periosteal Elevator Buser	4706	1	Q010599	MDR – Regulation 2017/745
118.	BONE EXPENDER CHISEL (B)	4801	1	Q010599	MDR – Regulation 2017/745
119.	BONE EXPENDER CHISEL (A)	4802	1	Q010599	MDR – Regulation 2017/745
120.	Castro Caliper 20mm 8.5cm	5001	1	Q010599	MDR – Regulation 2017/745
121.	Castro Caliper 40mm 8.5cm	5002	1	Q010599	MDR – Regulation 2017/745
122.	Castro Caliper 40mm 18cm	5003	1	Q010599	MDR – Regulation 2017/745
123.	Implant Gauge 80mm	5004	1	Q010599	MDR – Regulation 2017/745
124.	Crown Gauge	5005	1	Q010599	MDR – Regulation 2017/745
125.	Minesota Retractor	5101	1	Q010599	MDR – Regulation 2017/745
126.	Midledorpt Retractor	5102	1	Q010599	MDR – Regulation 2017/745
127.	Langenbeck Retractor	5103	1	Q010599	MDR – Regulation 2017/745
128.	Mirror -CS Type	5206	1	Q010599	MDR – Regulation 2017/745
129.	Dental mirror handle ø8	5207	1	Q010599	MDR – Regulation 2017/745
130.	Dental mirror handle ø10	5208	1	Q010599	MDR – Regulation 2017/745
131.	Dental mirror handle ø6	5209	1	Q010599	MDR – Regulation 2017/745
132.	Pincette	5301	1	Q010599	MDR – Regulation 2017/745
133.	Locking Pincette	5302	1	Q010599	MDR – Regulation 2017/745
134.	wide Pincette	5303	1	Q010599	MDR – Regulation 2017/745
135.	Articulator Holder	5306	1	Q010599	MDR – Regulation 2017/745
136.	Tissue Forceps Adson 12cm Str	5351	1	Q010599	MDR – Regulation 2017/745
137.	Tissue Forceps Adson 12cm (BROWN saw)	5352	1	Q010599	MDR – Regulation 2017/745

138.	Tissue Forceps Double Lock 15cm Cvd	5353	1	Q010599	MDR – Regulation 2017/745
139.	Tissue Forceps Semken 12.5cm (1x2) cvd	5354	1	Q010599	MDR – Regulation 2017/745
140.	Tissue Forceps Adson 15cm (1x2) Str	5355	1	Q010599	MDR – Regulation 2017/745
141.	Tissue Forceps Adson 12cm (1x2) Str	5356	1	Q010599	MDR – Regulation 2017/745
142.	Tissue Forceps Semken 14cm (1X2) Str	5357	1	Q010599	MDR – Regulation 2017/745
143.	Tissue Forceps MICRO 11.5cm Str	5358	1	Q010599	MDR – Regulation 2017/745
144.	Tissue Forceps MICRO 11.5cm Cvd	5359	1	Q010599	MDR – Regulation 2017/745
145.	Explorer	5401	1	Q010599	MDR – Regulation 2017/745
146.	Exprobe cp-15/23	5402	1	Q010599	MDR – Regulation 2017/745
147.	Mallet 16cm	5501	1	Q010599	MDR – Regulation 2017/745
148.	Suction silicone Line1.5m	5604	1	Q010599	MDR – Regulation 2017/745
149.	bone well	5700	1	Q010599	MDR – Regulation 2017/745
150.	Ochenbein (UP)	6201	1	Q010599	MDR – Regulation 2017/745
151.	Ochenbein (DOWN)	6202	1	Q010599	MDR – Regulation 2017/745
152.	Ochenbein (UNIVERSAL)	6203	1	Q010599	MDR – Regulation 2017/745
153.	Bone syringe Ø3.5/Ø4.5	7082	1	Q010599	MDR – Regulation 2017/745
154.	EASY MULTI NEEDLE HOLDER	1005	1	Q010599	MDR – Regulation 2017/745
155.	EASY CUTTING SCISSOR (STR)14cm	2111	1	Q010599	MDR – Regulation 2017/745
156.	EASY CUTTING SCISSOR (CVD)14cm	2112	1	Q010599	MDR – Regulation 2017/745
157.	EASY CUTTING SCISSOR (STR)16cm	2113	1	Q010599	MDR – Regulation 2017/745
158.	EASY CUTTING SCISSOR (CVD)16cm	2114	1	Q010599	MDR – Regulation 2017/745
159.	EASY LUX (STR,LEFT) 3mm	3111	1	Q010599	MDR – Regulation 2017/745
160.	EASY LUX (STR,RIGHT) 3mm	3112	1	Q010599	MDR – Regulation 2017/745
161.	EASY LUX (STR,LEFT) 4mm	3113	1	Q010599	MDR – Regulation 2017/745
162.	EASY LUX (STR,RIGHT) 4mm	3114	1	Q010599	MDR – Regulation 2017/745
163.	EASY LUX (CVD,LEFT) 4mm	3115	1	Q010599	MDR – Regulation 2017/745
164.	EASY LUX (CVD,RIGHT) 4mm	3116	1	Q010599	MDR – Regulation 2017/745
165.	IMPLANT FORCEP	3220	1	Q010599	MDR – Regulation 2017/745



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166.	EASY FORCEPS 150	3251	1	Q010599	MDR – Regulation 2017/745
167.	EASY FORCEPS 151	3252	1	Q010599	MDR – Regulation 2017/745
168.	EASY FORCEPS 222	3253	1	Q010599	MDR – Regulation 2017/745
169.	EASY FORCEP Root UNIVERSAL	3254	1	Q010599	MDR – Regulation 2017/745
170.	EASY PERIOTOME 2mm(Str)	3305	1	Q010599	MDR – Regulation 2017/745
171.	EASY PERIOTOME 3mm(Str)	3306	1	Q010599	MDR – Regulation 2017/745
172.	EASY PERIOTOME 2mm(Cur)	3307	1	Q010599	MDR – Regulation 2017/745
173.	EASY PERIOTOME 3mm(Cur)	3308	1	Q010599	MDR – Regulation 2017/745
174.	EASY PERIOTOME 2mm type-1	3311	1	Q010599	MDR – Regulation 2017/745
175.	EASY PERIOTOME 2mm type-2	3312	1	Q010599	MDR – Regulation 2017/745
176.	EASY IRRIGATION TUBE	5605	1	Q010599	MDR – Regulation 2017/745
177.	EASY FORCEPS Upper Anteriors	3251S	1	Q010599	MDR – Regulation 2017/745
178.	EASY FORCEPS Lower premolars	3252S	1	Q010599	MDR – Regulation 2017/745
179.	EASY FORCEPS Upper posteriors	3255S	1	Q010599	MDR – Regulation 2017/745
180.	EASY FORCEPS Lower Anteriors	3259S	1	Q010599	MDR – Regulation 2017/745
181.	Easy Sinus Window Flexible CURETTE 1	7091F	1	Q010599	MDR – Regulation 2017/745
182.	Easy Sinus Window Flexible CURETTE 2	7092F	1	Q010599	MDR – Regulation 2017/745
183.	Easy Sinus Window Flexible CURETTE 3	7093F	1	Q010599	MDR – Regulation 2017/745
184.	Easy Sinus Window Flexible CURETTE 4	7094F	1	Q010599	MDR – Regulation 2017/745
185.	Sinus Curette 1	7091	1	Q010599	MDR – Regulation 2017/745
186.	Sinus Curette 2	7092	1	Q010599	MDR – Regulation 2017/745
187.	Sinus Curette 3	7093	1	Q010599	MDR – Regulation 2017/745
188.	Sinus Curette 4	7094	1	Q010599	MDR – Regulation 2017/745
189.	Sinus Curette 5	7095	1	Q010599	MDR – Regulation 2017/745
190.	Bone syringe Ø5.0/Ø6.0	7081	1	Q010599	MDR – Regulation 2017/745
191.	Advenced Tissue forceps 18cm	5361	1	Q010599	MDR – Regulation 2017/745
192.	Advenced Tissue forceps 15.5cm	5362	1	Q010599	MDR – Regulation 2017/745
193.	Advenced Tissue forceps 17.5cm	5363	1	Q010599	MDR – Regulation 2017/745



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194.	Advanced Tissue forceps 12.5cm	5364	1	Q010599	MDR – Regulation 2017/745
195.	Mouth Gag 11cm	1052	1	Q010599	MDR – Regulation 2017/745
196.	Needle Holder 15cm STR	1105B	1	Q010599	MDR – Regulation 2017/745
197.	Needle Holder 15cm CVD	1106B	1	Q010599	MDR – Regulation 2017/745
198.	Needle Holder 18cm STR	1107B	1	Q010599	MDR – Regulation 2017/745
199.	Needle Holder 18cm CVD	1108B	1	Q010599	MDR – Regulation 2017/745
200.	Dual Blade Holder	4606	1	Q010599	MDR – Regulation 2017/745
201.	Root Picker Left (Thin Handle)	3016-1	1	Q010599	MDR – Regulation 2017/745
202.	Root Picker Right (Thin Handle)	3017-1	1	Q010599	MDR – Regulation 2017/745
203.	Surgical Curettes LUCAS86 2.9mm 2	4003S	1	Q010599	MDR – Regulation 2017/745
204.	Surgical Curettes MILLER11 3.5mm 2	4005S	1	Q010599	MDR – Regulation 2017/745
205.	Surgical Curettes Molt2/4 2	4007S	1	Q010599	MDR – Regulation 2017/745
206.	Periosteal Elevator Molt9 2	4701S	1	Q010599	MDR – Regulation 2017/745
207.	Periosteal Elevator Seldin 2	4703S	1	Q010599	MDR – Regulation 2017/745
208.	Periosteal Elevator P24G 2	4704S	1	Q010599	MDR – Regulation 2017/745
209.	Langenbeck Retractor 2	5103S	1	Q010599	MDR – Regulation 2017/745
210.	HEMOSTATS H4	1203B	1	Q010599	MDR – Regulation 2017/745
211.	HEMOSTATS H2	1204B	1	Q010599	MDR – Regulation 2017/745
212.	Needle Holder T/C 13cm Black	1100B	1	Q010599	MDR – Regulation 2017/745
213.	Needle Holder T/C 15cm Black	1102B	1	Q010599	MDR – Regulation 2017/745
214.	Needle Holder T/C 16cm Black	1103B	1	Q010599	MDR – Regulation 2017/745
215.	Cow Horn Minnesota Retractor	5101C	1	Q010599	MDR – Regulation 2017/745
216.	Mallet 16cm B type	5501B	1	Q010599	MDR – Regulation 2017/745
217.	Easy bone scraper	3500	1	Q010599	MDR – Regulation 2017/745
218.	Gracey Curette 1-2 (Titanium)	4101T	1	Q010599	MDR – Regulation 2017/745
219.	Gracey Curette 11-12 (Titanium)	4106T	1	Q010599	MDR – Regulation 2017/745
220.	Gracey Curette 13-14 (Titanium)	4107T	1	Q010599	MDR – Regulation 2017/745
221.	MULTI FORCEP	7101	1	Q010599	MDR – Regulation 2017/745



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222.	BONE CONDENSER	7102	1	Q010599	MDR – Regulation 2017/745
223.	TUNNELING GUIDE	7103	1	Q010599	MDR – Regulation 2017/745
224.	TUNNELING INITIAL ELEVATOR	7104	1	Q010599	MDR – Regulation 2017/745
225.	TUNNELING ADVANCE ELEVATOR	7105	1	Q010599	MDR – Regulation 2017/745
226.	Explorer (Black)	5401B	1	Q010599	MDR – Regulation 2017/745
227.	Explorer cp-15/23 (Black)	5402B	1	Q010599	MDR – Regulation 2017/745
228.	Easy Blade Holder	4607	1	Q010599	MDR – Regulation 2017/745
229.	Surgical Curettes LUCAS86 3.5mm	4009	1	Q010599	MDR – Regulation 2017/745
230.	Crown & Gold SCISSORS	1115	1	Q010599	MDR – Regulation 2017/745
231.	CROWN FORCEP	1116	1	Q010599	MDR – Regulation 2017/745
232.	Mini Friedman Bone Rongeurs	1304	1	Q010599	MDR – Regulation 2017/745
233.	Dual Edge Elevator 3.0/4.4mm	3105	1	Q010599	MDR – Regulation 2017/745
234.	Composit Instrument PFI 2	4052	1	Q010599	MDR – Regulation 2017/745
235.	Composit Instrument PFI 15	4053	1	Q010599	MDR – Regulation 2017/745
236.	Composit Instrument PFI 13	4054	1	Q010599	MDR – Regulation 2017/745
237.	Composit Instrument PFI 21B	4055	1	Q010599	MDR – Regulation 2017/745
238.	Composit Instrument CT1	4056	1	Q010599	MDR – Regulation 2017/745
239.	Composit Instrument CT7	4057	1	Q010599	MDR – Regulation 2017/745
240.	Composit Instrument CT10	4058	1	Q010599	MDR – Regulation 2017/745
241.	Composit Instrument COM11	4059	1	Q010599	MDR – Regulation 2017/745
242.	Amalgam Carriers Medium-Large	4060	1	Q010599	MDR – Regulation 2017/745
243.	Amalgam Pluggers 1-2	4061	1	Q010599	MDR – Regulation 2017/745
244.	Amalgam Pluggers 6-8	4062	1	Q010599	MDR – Regulation 2017/745
245.	Amalgam Burnishers Burn 28-29	4063	1	Q010599	MDR – Regulation 2017/745
246.	Probe - Williamas / Goldman Fox	4309	1	Q010599	MDR – Regulation 2017/745
247.	Periosteal Elevators Freer	4707	1	Q010599	MDR – Regulation 2017/745
248.	Matrix Retainers Tofflemire 3300	4901	1	Q010599	MDR – Regulation 2017/745
249.	Endo Locking Plier	5304	1	Q010599	MDR – Regulation 2017/745



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250.	Endo Explorer	5403	1	Q010599	MDR – Regulation 2017/745
251.	Root Canal Plugger 1-3	5404	1	Q010599	MDR – Regulation 2017/745
252.	Root Canal Plugger 5-7	5405	1	Q010599	MDR – Regulation 2017/745
253.	Root Canal Plugger 9-11	5406	1	Q010599	MDR – Regulation 2017/745
254.	Cord Packers Packing-1	5801	1	Q010599	MDR – Regulation 2017/745
255.	Cord Packers CSI-1 (SAW)	5802	1	Q010599	MDR – Regulation 2017/745
256.	Bone File Miller 1X	6001	1	Q010599	MDR – Regulation 2017/745
257.	Bone File Miller 21	6002	1	Q010599	MDR – Regulation 2017/745
258.	Rubber Dam Forceps	6101	1	Q010599	MDR – Regulation 2017/745
259.	Rubberdam Punch	6102	1	Q010599	MDR – Regulation 2017/745
260.	Rubber Dam Frame	6103	1	Q010599	MDR – Regulation 2017/745
261.	Sterilizing Forceps	8001	1	Q010599	MDR – Regulation 2017/745
262.	Alginate Spatulas	8002	1	Q010599	MDR – Regulation 2017/745
263.	Bone Well 2	5701	1	Q010599	MDR – Regulation 2017/745
264.	Easy Surgical 360° Suction	5603	1	Q010599	MDR – Regulation 2017/745
265.	Sterilization Cloth (KIT S)	7071-1	1	Q010599	MDR – Regulation 2017/745
266.	Sterilization Cloth (KIT L)	7071-2	1	Q010599	MDR – Regulation 2017/745
267.	Suction Cloth	7071-3	1	Q010599	MDR – Regulation 2017/745
268.	Sterilization Cloth (Extraction Set Cloth)	7071-4	1	Q010599	MDR – Regulation 2017/745