

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Manufacture: DMAX Co., Ltd.

89, Hosan-ro, Dalseo-gu, Daegu, 42710, Korea

SRN: KR-MF-000020635

EC Representative: Emergo Europe B.V.

Westervoortsedijk 60 6827 AT Arnhem The Netherlands

Product Name: Liquid stain for dental zirconium prosthesis

(Brand: DMAX coloring liquid, Confident coloring liquid, CAMEleon coloring liquid)

Model Name: Total 410 types including A1-15ml (refer to Annex A)

Basic UDI-DI: 880954203LD00FP

Classification : Class IIa (Annex IX Rule 8, MDD 93/42/EEC)

Conformity Assessment Route : Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Standards applied: EN ISO13485:2016/AC11:2021, EN ISO14971:2019/AC11:2021, EN ISO10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN 1641:2009, EN ISO 15223-1:2021, EN 62366-1:2015, EN ISO 7405:2018, ISO/TR 24971:2020, EN ISO 7491:2000, EN ISO 10271: 2020, EN ISO 20417:2021, ISTA Procedure 2A, ASTM F1980-21, MEDDEV.2.7.1 Rev.4, MEDDEV 2.12 Rev.8

Notified Body : SGS Belgium NV, 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

EC Certificate No.: KR19/81826252

Signature :



CE 1639

Name/Title: Tae-Seok, Park / CEO

Date of Issue: September 26, 2023

Place : Korea, republic of

Annex A

Product Name: Liquid stain for dental zirconium prosthesis

Brand Name: DMAX coloring liquid, Confident coloring liquid, CAMEleon coloring liquid

Model Name: Total 410 types including A1-15ml

No	Model name	DI	No	Model name	DI
1	A1-15ml	08809542033161	46	Dark blue-15ml	08809542033611
2	A2-15ml	08809542033178	47	Dark Gray-15ml	08809542033628
3	A3-15ml	08809542033185	48	Enamel-15ml	08809542033635
4	A3.5-15ml	08809542033192	49	Orange Brown-15ml	08809542033642
5	A4-15ml	08809542033208	50	Osaka blue-15ml	08809542033659
6	B1-15ml	08809542033215	51	Osaka Gray-15ml	08809542033666
7	B2-15ml	08809542033222	52	Mamelon Lite-15ml	08809542033673
8	B3-15ml	08809542033239	53	Mamelon Dark-15ml	08809542033680
9	B4-15ml	08809542033246	54	V1-15ml	08809542033697
10	C1-15ml	08809542033253	55	V2-15ml	08809542033703
11	C2-15ml	08809542033260	56	V3-15ml	08809542033710
12	C3-15ml	08809542033277	57	1M1-15ml	08809542033727
13	C4-15ml	08809542033284	58	1M2-15ml	08809542033734
14	D2-15ml	08809542033291	59	2L1.5-15ml	08809542033741
15	D3-15ml	08809542033307	60	2L2.5-15ml	08809542033758
16	D4-15ml	08809542033314	61	2M1-15ml	08809542033765
17	Deep dentine DA Lite-15ml	08809542033321	62	2M2-15ml	08809542033772
18	Deep dentine DB Lite-15ml	08809542033338	63	2M3-15ml	08809542033789
19	Deep dentine DC Lite-15ml	08809542033345	64	2R1.5-15ml	08809542033796
20	Deep dentine DD Lite-15ml	08809542033352	65	2R2.5-15ml	08809542033802
21	Deep dentine DA Dark-15ml	08809542033369	66	3L1.5-15ml	08809542033819
22	Deep dentine DB Dark-15ml	08809542033376	67	3L2.5-15ml	08809542033826
23	Deep dentine DC Dark-15ml	08809542033383	68	3M1-15ml	08809542033833
24	Deep dentine DD Dark-15ml	08809542033390	69	3M2-15ml	08809542033840
25	Brown-15ml	08809542033406	70	3M3-15ml	08809542033857
26	Blue-15ml	08809542033413	71	3R1.5-15ml	08809542033864
27	Fluorescence-15ml	08809542033420	72	3R2.5-15ml	08809542033871
28	White-15ml	08809542033437	73	4L1.5-15ml	08809542033888
29	White Plus-15ml	08809542033444	74	4L2.5-15ml	08809542033895
30	Opal White-15ml	08809542033451	75	4M1-15ml	08809542033901
31	Opal-15ml	08809542033468	76	4M2-15ml	08809542033918
32	Gray-15ml	08809542033475	77	4M3-15ml	08809542033925
33	Gray Violet-15ml	08809542033482	78	4R1.5-15ml	08809542033932
34	Orange-15ml	08809542033499	79	4R2.5-15ml	08809542033949
35	Orange Yellow-15ml	08809542033505	80	5M1-15ml	08809542033956
36	Orange Pink-15ml	08809542033512	81	5M2-15ml	08809542033963
37	Pink-15ml	08809542033529	82	5M3-15ml	08809542033970
38	Young Trans-15ml	08809542033536	83	A1-20ml	08809542033987
39	Old Trans-15ml	08809542033543	84	A2-20ml	08809542033994
40	T-Glass Blue-15ml	08809542033550	85	A3-20ml	08809542034007
41	T-Glass Gray-15ml	08809542033567	86	A3.5-20ml	08809542034014
42	Ice Blue-15ml	08809542033574	87	A4-20ml	08809542034021
43	Ice Gray-15ml	08809542033581	88	B1-20ml	08809542034038
44	Dipping A3-15ml	08809542033598	89	B2-20ml	08809542034045
45	Dipping A4-15ml	08809542033604	90	B3-20ml	08809542034052

No	Model name	DI	No	Model name	DI
91	B4-20ml	08809542034069	136	V1-20ml	08809542034519
92	C1-20ml	08809542034076	137	V2-20ml	08809542034526
93	C2-20ml	08809542034083	138	V3-20ml	08809542034533
94	C3-20ml	08809542034090	139	1M1-20ml	08809542034540
95	C4-20ml	08809542034106	140	1M2-20ml	08809542034557
96	D2-20ml	08809542034113	141	2L1.5-20ml	08809542034564
97	D3-20ml	08809542034120	142	2L2.5-20ml	08809542034571
98	D4-20ml	08809542034137	143	2M1-20ml	08809542034588
99	Deep dentine DA Lite-20ml	08809542034144	144	2M2-20ml	08809542034595
100	Deep dentine DB Lite-20ml	08809542034151	145	2M3-20ml	08809542034601
101	Deep dentine DC Lite-20ml	08809542034168	146	2R1.5-20ml	08809542034618
102	Deep dentine DD Lite-20ml	08809542034175	147	2R2.5-20ml	08809542034625
103	Deep dentine DA Dark-20ml	08809542034182	148	3L1.5-20ml	08809542034632
104	Deep dentine DB Dark-20ml	08809542034199	149	3L2.5-20ml	08809542034649
105	Deep dentine DC Dark-20ml	08809542034205	150	3M1-20ml	08809542034656
106	Deep dentine DD Dark-20ml	08809542034212	151	3M2-20ml	08809542034663
107	Brown-20ml	08809542034229	152	3M3-20ml	08809542034670
108	Blue-20ml	08809542034236	153	3R1.5-20ml	08809542034687
109	Fluorescence-20ml	08809542034243	154	3R2.5-20ml	08809542034694
110	White-20ml	08809542034250	155	4L1.5-20ml	08809542034700
111	White Plus-20ml	08809542034267	156	4L2.5-20ml	08809542034717
112	Opal White-20ml	08809542034274	157	4M1-20ml	08809542034724
113	Opal-20ml	08809542034281	158	4M2-20ml	08809542034731
114	Gray-20ml	08809542034298	159	4M3-20ml	08809542034748
115	Gray Violet-20ml	08809542034304	160	4R1.5-20ml	08809542034755
116	Orange-20ml	08809542034311	161	4R2.5-20ml	08809542034762
117	Orange Yellow-20ml	08809542034328	162	5M1-20ml	08809542034779
118	Orange Pink-20ml	08809542034335	163	5M2-20ml	08809542034786
119	Pink-20ml	08809542034342	164	5M3-20ml	08809542034793
120	Young Trans-20ml	08809542034359	165	A1-30ml	08809542034809
121	Old Trans-20ml	08809542034366	166	A2-30ml	08809542034816
122	T-Glass Blue-20ml	08809542034373	167	A3-30ml	08809542034823
123	T-Glass Gray-20ml	08809542034380	168	A3.5-30ml	08809542034830
124	Ice Blue-20ml	08809542034397	169	A4-30ml	08809542034847
125	Ice Gray-20ml	08809542034403	170	B1-30ml	08809542034854
126	Dipping A3-20ml	08809542034410	171	B2-30ml	08809542034861
127	Dipping A4-20ml	08809542034427	172	B3-30ml	08809542034878
128	Dark blue-20ml	08809542034434	173	B4-30ml	08809542034885
129	Dark Gray-20ml	08809542034441	174	C1-30ml	08809542034892
130	Enamel-20ml	08809542034458	175	C2-30ml	08809542034908
131	Orange Brown-20ml	08809542034465	176	C3-30ml	08809542034915
132	Osaka blue-20ml	08809542034472	177	C4-30ml	08809542034922
133	Osaka Gray-20ml	08809542034489	178	D2-30ml	08809542034939
134	Mamelon Lite-20ml	08809542034496	179	D3-30ml	08809542034946
135	Mamelon Dark-20ml	08809542034502	180	D4-30ml	08809542034953

No	Model name	DI	No	Model name	DI
181	Deep dentine DA Lite-30ml	08809542034960	226	2M2-30ml	08809542035417
182	Deep dentine DB Lite-30ml	08809542034977	227	2M3-30ml	08809542035424
183	Deep dentine DC Lite-30ml	08809542034984	228	2R1.5-30ml	08809542035431
184	Deep dentine DD Lite-30ml	08809542034991	229	2R2.5-30ml	08809542035448
185	Deep dentine DA Dark-30ml	08809542035004	230	3L1.5-30ml	08809542035455
186	Deep dentine DB Dark-30ml	08809542035011	231	3L2.5-30ml	08809542035462
187	Deep dentine DC Dark-30ml	08809542035028	232	3M1-30ml	08809542035479
188	Deep dentine DD Dark-30ml	08809542035035	233	3M2-30ml	08809542035486
189	Brown-30ml	08809542035042	234	3M3-30ml	08809542035493
190	Blue-30ml	08809542035059	235	3R1.5-30ml	08809542035509
191	Fluorescence-30ml	08809542035066	236	3R2.5-30ml	08809542035516
192	White-30ml	08809542035073	237	4L1.5-30ml	08809542035523
193	White Plus-30ml	08809542035080	238	4L2.5-30ml	08809542035530
194	Opal White-30ml	08809542035097	239	4M1-30ml	08809542035547
195	Opal-30ml	08809542035103	240	4M2-30ml	08809542035554
196	Gray-30ml	08809542035110	241	4M3-30ml	08809542035561
197	Gray Violet-30ml	08809542035127	242	4R1.5-30ml	08809542035578
198	Orange-30ml	08809542035134	243	4R2.5-30ml	08809542035585
199	Orange Yellow-30ml	08809542035141	244	5M1-30ml	08809542035592
200	Orange Pink-30ml	08809542035158	245	5M2-30ml	08809542035608
201	Pink-30ml	08809542035165	246	5M3-30ml	08809542035615
202	Young Trans-30ml	08809542035172	247	A1-40ml	08809542035622
203	Old Trans-30ml	08809542035189	248	A2-40ml	08809542035639
204	T-Glass Blue-30ml	08809542035196	249	A3-40ml	08809542035646
205	T-Glass Gray-30ml	08809542035202	250	A3.5-40ml	08809542035653
206	Ice Blue-30ml	08809542035219	251	A4-40ml	08809542035660
207	Ice Gray-30ml	08809542035226	252	B1-40ml	08809542035677
208	Dipping A3-30ml	08809542035233	253	B2-40ml	08809542035684
209	Dipping A4-30ml	08809542035240	254	B3-40ml	08809542035691
210	Dark blue-30ml	08809542035257	255	B4-40ml	08809542035707
211	Dark Gray-30ml	08809542035264	256	C1-40ml	08809542035714
212	Enamel-30ml	08809542035271	257	C2-40ml	08809542035721
213	Orange Brown-30ml	08809542035288	258	C3-40ml	08809542035738
214	Osaka blue-30ml	08809542035295	259	C4-40ml	08809542035745
215	Osaka Gray-30ml	08809542035301	260	D2-40ml	08809542035752
216	Mamelon Lite-30ml	08809542035318	261	D3-40ml	08809542035769
217	Mamelon Dark-30ml	08809542035325	262	D4-40ml	08809542035776
218	V1-30ml	08809542035332	263	Deep dentine DA Lite-40ml	08809542035783
219	V2-30ml	08809542035349	264	Deep dentine DB Lite-40ml	08809542035790
220	V3-30ml	08809542035356	265	Deep dentine DC Lite-40ml	08809542035806
221	1M1-30ml	08809542035363	266	Deep dentine DD Lite-40ml	08809542035813
222	1M2-30ml	08809542035370	267	Deep dentine DA Dark-40ml	08809542035820
223	2L1.5-30ml	08809542035387	268	Deep dentine DB Dark-40ml	08809542035837
224	2L2.5-30ml	08809542035394	269	Deep dentine DC Dark-40ml	08809542035844
225	2M1-30ml	08809542035400	270	Deep dentine DD Dark-40ml	08809542035851

No	Model name	DI	No	Model name	DI
271	Brown-40ml	08809542035868	316	3M3-40ml	08809542036315
272	Blue-40ml	08809542035875	317	3R1.5-40ml	08809542036322
273	Fluorescence-40ml	08809542035882	318	3R2.5-40ml	08809542036339
274	White-40ml	08809542035899	319	4L1.5-40ml	08809542036346
275	White Plus-40ml	08809542035905	320	4L2.5-40ml	08809542036353
276	Opal White-40ml	08809542035912	321	4M1-40ml	08809542036360
277	Opal-40ml	08809542035929	322	4M2-40ml	08809542036377
278	Gray-40ml	08809542035936	323	4M3-40ml	08809542036384
279	Gray Violet-40ml	08809542035943	324	4R1.5-40ml	08809542036391
280	Orange-40ml	08809542035950	325	4R2.5-40ml	08809542036407
281	Orange Yellow-40ml	08809542035967	326	5M1-40ml	08809542036414
282	Orange Pink-40ml	08809542035974	327	5M2-40ml	08809542036421
283	Pink-40ml	08809542035981	328	5M3-40ml	08809542036438
284	Young Trans-40ml	08809542035998	329	A1-100ml	08809542036445
285	Old Trans-40ml	08809542036001	330	A2-100ml	08809542036452
286	T-Glass Blue-40ml	08809542036018	331	A3-100ml	08809542036469
287	T-Glass Gray-40ml	08809542036025	332	A3.5-100ml	08809542036476
288	Ice Blue-40ml	08809542036032	333	A4-100ml	08809542036483
289	Ice Gray-40ml	08809542036049	334	B1-100ml	08809542036490
290	Dipping A3-40ml	08809542036056	335	B2-100ml	08809542036506
291	Dipping A4-40ml	08809542036063	336	B3-100ml	08809542036513
292	Dark blue-40ml	08809542036070	337	B4-100ml	08809542036520
293	Dark Gray-40ml	08809542036087	338	C1-100ml	08809542036537
294	Enamel-40ml	08809542036094	339	C2-100ml	08809542036544
295	Orange Brown-40ml	08809542036100	340	C3-100ml	08809542036551
296	Osaka blue-40ml	08809542036117	341	C4-100ml	08809542036568
297	Osaka Gray-40ml	08809542036124	342	D2-100ml	08809542036575
298	Mamelon Lite-40ml	08809542036131	343	D3-100ml	08809542036582
299	Mamelon Dark-40ml	08809542036148	344	D4-100ml	08809542036599
300	V1-40ml	08809542036155	345	Deep dentine DA Lite-100ml	08809542036605
301	V2-40ml	08809542036162	346	Deep dentine DB Lite-100ml	08809542036612
302	V3-40ml	08809542036179	347	Deep dentine DC Lite-100ml	08809542036629
303	1M1-40ml	08809542036186	348	Deep dentine DD Lite-100ml	08809542036636
304	1M2-40ml	08809542036193	349	Deep dentine DA Dark-100ml	08809542036643
305	2L1.5-40ml	08809542036209	350	Deep dentine DB Dark-100ml	08809542036650
306	2L2.5-40ml	08809542036216	351	Deep dentine DC Dark-100ml	08809542036667
307	2M1-40ml	08809542036223	352	Deep dentine DD Dark-100ml	08809542036674
308	2M2-40ml	08809542036230	353	Brown-100ml	08809542036681
309	2M3-40ml	08809542036247	354	Blue-100ml	08809542036698
310	2R1.5-40ml	08809542036254	355	Fluorescence-100ml	08809542036704
311	2R2.5-40ml	08809542036261	356	White-100ml	08809542036711
312	3L1.5-40ml	08809542036278	357	White Plus-100ml	08809542036728
313	3L2.5-40ml	08809542036285	358	Opal White-100ml	08809542036735
314	3M1-40ml	08809542036292	359	Opal-100ml	08809542036742
315	3M2-40ml	08809542036308	360	Gray-100ml	08809542036759

No	Model name	DI	No	Model name	DI
361	Gray Violet-100ml	08809542036766	406	4R1.5-100ml	08809542037213
362	Orange-100ml	08809542036773	407	4R2.5-100ml	08809542037220
363	Orange Yellow-100ml	08809542036780	408	5M1-100ml	08809542037237
364	Orange Pink-100ml	08809542036797	409	5M2-100ml	08809542037244
365	Pink-100ml	08809542036803	410	5M3-100ml	08809542037251
366	Young Trans-100ml	08809542036810			
367	Old Trans-100ml	08809542036827			
368	T-Glass Blue-100ml	08809542036834			
369	T-Glass Gray-100ml	08809542036841			
370	Ice Blue-100ml	08809542036858			
371	Ice Gray-100ml	08809542036865			
372	Dipping A3-100ml	08809542036872			
373	Dipping A4-100ml	08809542036889			
374	Dark blue-100ml	08809542036896			
375	Dark Gray-100ml	08809542036902			
376	Enamel-100ml	08809542036919			
377	Orange Brown-100ml	08809542036926			
378	Osaka blue-100ml	08809542036933			
379	Osaka Gray-100ml	08809542036940			
380	Mamelon Lite-100ml	08809542036957			
381	Mamelon Dark-100ml	08809542036964			
382	V1-100ml	08809542036971			
383	V2-100ml	08809542036988			
384	V3-100ml	08809542036995			
385	1M1-100ml	08809542037008			
386	1M2-100ml	08809542037015			
387	2L1.5-100ml	08809542037022			
388	2L2.5-100ml	08809542037039			
389	2M1-100ml	08809542037046			
390	2M2-100ml	08809542037053			
391	2M3-100ml	08809542037060			
392	2R1.5-100ml	08809542037077			
393	2R2.5-100ml	08809542037084			
394	3L1.5-100ml	08809542037091			
395	3L2.5-100ml	08809542037107			
396	3M1-100ml	08809542037114			
397	3M2-100ml	08809542037121			
398	3M3-100ml	08809542037138			
399	3R1.5-100ml	08809542037145			
400	3R2.5-100ml	08809542037152			
401	4L1.5-100ml	08809542037169			
402	4L2.5-100ml	08809542037176			
403	4M1-100ml	08809542037183			
404	4M2-100ml	08809542037190			
405	4M3-100ml	08809542037206			