

# DECLARATION OF CONFORMANCE

Manufacturer: Tokuyama Dental Corporation  
Address: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo 110-0016, Japan

European representative: Tokuyama Dental Italy S.r.l.  
Address: Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy

Product name: PALFIQUE ESTELITE  
, including the following 13 products.  
PALFIQUE ESTELITE PASTE SYRINGE  
ESTELITE  $\Sigma$  QUICK SYRINGE  
ESTELITE  $\Sigma$  QUICK PLT  
ESTELITE POSTERIOR  
ESTELITE ASTERIA SYRINGE  
ESTELITE ASTERIA PLT  
ESTELITE COLOR  
ESTELITE BULK FILL Flow SYRINGE  
ESTELITE BULK FILL Flow PLT  
ESTELITE UNIVERSAL FLOW SYRINGE  
ESTELITE UNIVERSAL FLOW PLT  
OMNICHROMA BLOCKER SYRINGE  
OMNICHROMA BLOCKER PLT

Reference No.: PE01

Classification (MDD, Annex IX): Class IIa (Rule 8)

First Shipment Date: 5 November, 2019  
First lot Number: see attached sheet 1

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

## DIRECTIVES and REGULATION

General applicable directive and regulation:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC

Regulation concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), 1907/2006/EC

Standards: see attached sheet 2

Notified Body: Notified Body Number 1639  
SGS Belgium NV


Address: SGS House Noorderlaan 87 2030 Antwerp Belgium

Certificate: JP19/040508 (Annex II (excluding Section 4) MDD)

Place: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo 110-0016, Japan

Date: 1 April 2022

Signature

  
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Masatsugu Kusano  
Factory Manager

First lot number for refill:

Article		First lot number in EU market	First shipment date	Article No.
PALFIQUE ESTELITE PASTE (syringe) 3.8g	A1	206EY9	5 November 2019	11310
		--- 1)	--- 1)	11353
	A2	296EY9	5 November 2019	11311
		--- 1)	--- 1)	11354
	A3	285EY9	5 November 2019	11312
		--- 1)	--- 1)	11355
	A3.5	203E10	7 January 2020	11313
		--- 1)	--- 1)	11356
	Incisal	095E10	7 January 2020	11320
		--- 1)	--- 1)	11359
	B2	137E10	7 January 2020	11314
		--- 1)	--- 1)	11357
	B3	--- 1)	--- 1)	---
	B4	--- 1)	--- 1)	---
	C1	--- 1)	--- 1)	---
	C2	101E10	7 January 2020	11318
		--- 1)	--- 1)	11358
	C3	--- 1)	--- 1)	---
	Cervical	--- 1)	--- 1)	---
	OA1	--- 1)	--- 1)	---
OA2	277E10	7 January 2020	11322	
	--- 1)	--- 1)	11360	
OA3	270E10	7 January 2020	11324	
	--- 1)	--- 1)	11361	

1) Detailed lot number and first shipment date are not fixed at the present moment.

First lot number for kit:

Article	First lot number in EU market	First shipment date	Article No.
ESTELITE Σ QUICK 3 Syringe kit 3.8g x 3	107EY9	5 November 2019	13104
ESTELITE Σ QUICK SYRINGE Promo kit 3.8g x 6	075EZ9	5 December 2019	13105
ESTELITE Σ QUICK SYRINGE INTRO KIT II 3.8g x 6	105EY9	5 November 2019	13204
ESTELITE Σ QUICK PLT INTRO KIT II 0.2g x 40	068EZ9	5 December 2019	13305

First lot number for refill:

Article		First lot number in EU market	First shipment date	Article No.	
				Importer	
				Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE $\Sigma$ QUICK SYRINGE 3.8g	A1	119EY9, 133EY9	5 November 2019	13210	13130
	A2	151EY9, 169EY9	5 November 2019	13211	13131
	A3	178EY9, 182EY9	5 November 2019	13212	13132
	A3.5	138EY9, 150EY9	5 November 2019	13213	13133
	A4	118EY9, 119EY9	5 November 2019	13214	13134
	A5	086EY9	5 November 2019	13215	13135
	B1	093EY9, 097EY9	5 November 2019	13216	13136
	B2	096EY9, 131EY9	5 November 2019	13217	13137
	B3	079EY9, 122EY9	5 November 2019	13218	13138
	B4	045EY9, 069EY9	5 November 2019	13219	13139
	C1	052EY9	5 November 2019	13220	13140
	C2	101EY9	5 November 2019	13221	13141
	C3	078EY9, 095EY9	5 November 2019	13222	13142
	OA1	087EY9, 107EY9	5 November 2019	13223	13143
	OA2	122EY9, 141EY9	5 November 2019	13224	13144
	OA3	114EY9, 142EY9	5 November 2019	13225	13145
	OPA2	095EY9, 109EY9	5 November 2019	13226	13146
	BW	108EY9	5 November 2019	13228	13148
	WE	087EY9	20 November 2019	13229	13149
CE	077EY9, 098EY9	5 November 2019	13227	13147	
ESTELITE $\Sigma$ QUICK SYRINGE Mini 1g	A2	047E30, 048E30	5 March 2020	13197	13192
	A3	039E30	5 March 2020	13198	13195
ESTELITE $\Sigma$ QUICK PLT 0.2g x 20	A1	118EY9, 156EY9	5 November 2019	13250	13330
	A2	151EY9, 223EY9	5 November 2019	13251	13331
	A3	284EY9, 285EY9	5 November 2019	13252	13332
	A3.5	098EY9, 204EY9	5 November 2019	13253	13333
	A4	087EY9, 160EY9	5 November 2019	13254	13334
	A5	100EY9	5 November 2019	13255	13335
	B1	096EY9	5 November 2019	13256	13336
	B2	077EY9	20 November 2019	13257	13337
	B3	075EY9, 147EY9	5 November 2019	13258	13338
	B4	027E10	7 January 2020	13259	13339
	C1	046E10	7 January 2020	13260	13340
	C2	071EY9, 132EY9	5 November 2019	13261	13341
	C3	053EY9	20 November 2019	13262	13342
	OA1	094EZ9	5 December 2019	13263	13343
	OA2	150EY9	5 November 2019	13264	13344
	OA3	109EY9, 189EY9	5 November 2019	13265	13345
	OPA2	124EY9	20 November 2019	13266	13346
	BW	085EY9, 087EY9	5 November 2019	13268	13348
	WE	028EY9	5 November 2019	13269	13349
CE	081EZ9	5 December 2019	13267	13347	
ESTELITE $\Sigma$ QUICK PLT Mini 0.2gx5	A2	--- 1)	--- 1)	13397	13392
	A3	061E40	6 April 2020	13398	13395

1) Detailed lot number and first shipment date are not fixed at the present moment.

First lot number for refill:

Article		First lot number in EU market	First shipment date	Article No.	
				Importer	
				Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE POSTERIOR 4.2g	PCE	067EY9	5 November 2019	12909	12924
	PA1	013EY9	5 November 2019	12906	12921
	PA2	019EY9, 129EY9	5 November 2019	12907	12922
	PA3	021EY9, 137EY9	5 November 2019	12908	12923

First lot number for kit:

Article	First lot number in EU market	First shipment date	Article No.	
			Importer	
			Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE ASTERIA SYRINGE essential kit 4.0g x 7	146EY9	5 November 2019	10931	10932
ESTELITE ASTERIA PLT essential kit 0.2g x 105	030EY9	5 November 2019	10396	10397

First lot number for refill:

		First lot number in EU market	First shipment date	Article No.	
				Importer	
				Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE ASTERIA SYRINGE 4.0g	A1B	122EY9, 123EY9	5 November 2019	10941	10961
	A2B	140EY9, 149EY9	5 November 2019	10942	10962
	A3B	143EY9, 154EY9	5 November 2019	10943	10963
	A3.5B	114EY9, 132EY9	5 November 2019	10944	10964
	A4B	058EY9	5 November 2019	10945	10965
	B3B	094EY9	5 November 2019	10946	10966
	BL	102EY9	5 November 2019	10947	10967
	NE	125EY9, 132EY9	5 November 2019	10948	10968
	WE	114EY9, 129EY9	5 November 2019	10949	10969
	YE	085EY9	5 November 2019	10950	10970
	TE	063EY9, 090EY9	5 November 2019	10951	10971
OcE	108EY9, 119EY9	5 November 2019	10952	10972	
ESTELITE ASTERIA PLT 0.2g x 15	A1B	027EY9	5 November 2019	10365	10380
	A2B	035EY9	5 November 2019	10366	10381
	A3B	045EY9	5 November 2019	10367	10382
	A3.5B	025EY9	5 November 2019	10368	10383
	A4B	017EY9, 018EY9	5 November 2019	10369	10384
	B3B	010E30	5 March 2020	10370	10385
	BL	017EY9	5 November 2019	10371	10386
	NE	030EY9	5 November 2019	10372	10387
	WE	020EY9, 023EY9	5 November 2019	10373	10388
	YE	012E10	7 January 2020	10374	10389
	TE	014E30	5 March 2020	10375	10390
	OcE	023EY9	5 November 2019	10376	10391

First lot number for kit:

Article	First lot number in EU market	First shipment date	Article No.	
			Importer	
			Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE COLOR kit 0.9g x 13	066EZ9	5 December 2019	10831	10832

First lot number for refill:

Article	First lot number in EU market	First shipment date	Article No.		
			Importer		
			Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH	
ESTELITE COLOR 0.9g	Clear	030EY9	5 November 2019	10841	10861
	White	078EY9	5 November 2019	10842	10862
	Blue	047EY9	5 November 2019	10843	10863
	Yellow	028E20	20 February 2020	10844	10864
	Gray	048EZ9	5 December 2019	10845	10865
	Ochre	059EY9	5 November 2019	10846	10866
	Dark Brown	068EY9	5 November 2019	10847	10867
	Red	024E00	20 October 2020	10848	10868
	Lavender	021EY9	5 November 2019	10849	10869
	Pink Opaque	065EY9	20 November 2019	10850	10870
	High Chroma Opaque	063EY9	20 November 2019	10851	10871
	Medium Chroma Opaque	063EY9	5 November 2019	10852	10872
	Low Chroma Opaque	032EY9	20 November 2019	10853	10873

First lot number for refill:

Article		First lot number in EU market	First shipment date	Article No.	
				Importer	
				Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE BULK FILL Flow SYRINGE 3.0g	Universal	028EY9, 050EY9	5 November 2019	12700	12705
	B1	024EY9	5 November 2019	12701	12706
	A1	028EY9, 049EY9	5 November 2019	12702	12707
	A2	072EY9, 076EY9	5 November 2019	12703	12708
	A3	068EY9, 088EY9	5 November 2019	12704	12709
ESTELITE BULK FILL Flow PLT 0.2gx20	Universal	021EY9	5 November 2019	12720	12725
	B1	006EZ9, 017EZ9	5 December 2019	12721	12726
	A1	007EY9	5 November 2019	12722	12727
	A2	042EY9, 048EY9	5 November 2019	12723	12728
	A3	037EY9, 049EY9, 050EY9	5 November 2019	12724	12729

First lot number for refill:

Article		First lot number in EU market	First shipment date	Article No.	
				Importer	
				Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
ESTELITE UNIVERSAL FLOW High L-SYR 3.0g	A1	021EY9, 023EY9	5 November 2019	13800	13825
	A2	027EY9, 031EY9	5 November 2019	13801	13826
	A3	026EY9, 031EY9	5 November 2019	13802	13827
	A3.5	012EY9	5 November 2019	13803	13828
	OPA2	014EY9	5 November 2019	13804	13829
	OPA3	015EY9	20 November 2019	13805	13830
	OPA4	008EY9	5 November 2019	13806	13831
ESTELITE UNIVERSAL FLOW Medium L-SYR 3.0g	A1	024EY9	5 November 2019	13807	13832
	A2	042EY9	5 November 2019	13808	13833
	A3	037EY9	5 November 2019	13809	13834
	A3.5	027EY9	5 November 2019	13810	13835
	A4	017EY9	5 November 2019	13811	13836
	A5	009E20	20 February 2020	13812	13837
	B3	009EZ9, 010EZ9	5 December 2019	13813	13838
	OPA2	024EY9	5 November 2019	13814	13839
	OPA3	026EY9	5 November 2019	13815	13840
	OPA4	010EY9	5 November 2019	13816	13841
	CE	011EY9	5 November 2019	13817	13842
BW	010EY9	5 November 2019	13818	13843	
ESTELITE UNIVERSAL FLOW SuperLow L-SYR 3.0g	A1	014EY9, 015EY9	5 November 2019	13819	13844
	A2	021EY9, 033EY9	5 November 2019	13820	13845
	A3	024EY9, 031EY9	5 November 2019	13821	13846
	A3.5	014EY9	5 November 2019	13822	13847
	A4	015EY9	5 November 2019	13823	13848
	A5	009EZ9	5 December 2019	13824	13849
ESTELITE UNIVERSAL FLOW Medium SYRINGE 1.7g	A1	014EY9, 017EY9	5 November 2019	13640	13652
	A2	019EY9, 024EY9	5 November 2019	13641	13653
	A3	022EY9, 037EY9	5 November 2019	13642	13654
	A3.5	018EY9, 021EY9	5 November 2019	13643	13655
	A4	013EY9, 015EY9	5 November 2019	13644	13656
	A5	009EZ9	5 December 2019	13645	13657
	B3	007EY9	5 November 2019	13646	13658
	OPA2	017EY9, 018EY9	5 November 2019	13647	13659
	OPA3	019EY9, 025EY9	5 November 2019	13648	13660
	OPA4	006EY9	20 November 2019	13649	13661
	CE	011EY9	5 November 2019	13650	13662
	BW	013EY9	5 November 2019	13651	13663
	ESTELITE UNIVERSAL FLOW Medium PLT 0.2g x 20	A1	010EY9	5 November 2019	13907
A2		018EY9	5 November 2019	13908	13933
A3		026EY9	5 November 2019	13909	13934
A3.5		015EY9	5 November 2019	13910	13935
A4		006E70	6 July 2020	13911	13936
A5		002EY0	5 November 2020	13912	13937
B3		005EY9	5 November 2019	13913	13938
OPA2		014E10	7 January 2020	13914	13939
OPA3		012E10	7 January 2020	13915	13940
OPA4		002E90	3 September 2020	13916	13941
CE		004E90	3 September 2020	13917	13942
BW		005E30	5 March 2020	13918	13943

First lot number for refill:

Article	First lot number in EU market	First shipment date	Article No.	
			Importer	
			Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
OMNICHROMA BLOCKER SYRINGE 4g	012EY9	5 November 2019	10111	10113
OMNICHROMA BLOCKER PLT 0.2g x 20	009EY9, 012EY9	5 November 2019	10121	10123

First lot number for accessory:

Article	First lot number in EU market	First shipment date	Article No.
TOKUYAMA Dispensing Tip <sup>1)</sup> x 50	021EZ9	7 January 2020	12740
	--- 2)	--- 2)	12745
TOKUYAMA Plastic Tip <sup>1)</sup> x 50	021EY9	5 November 2019	13799

1) Accessories listed above are not included within the scope of this declaration, listed for reference only.

2) Detailed lot number and first shipment date are not fixed at the present moment.

Standards applied to this product are listed below.

Standard	Published year
EN ISO 10993-1	2009
EN ISO 10993-3	2014
EN ISO 10993-5	2009
ISO 10993-10	2010
EN ISO 10993-11	2018
EN ISO 10993-12	2012
EN ISO 10993-18	2020
EN ISO 13485	2016
EN ISO 14971	2012
EN 1041	2008
EN 1641	2009
ISO 7405	2008
EN ISO 15223-1	2021
ISO 4049	2019
JIS T 6514	2015