

DECLARATION OF CONFORMANCE

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

European representative: Tokuyama Dental Italy S.r.l.
Address: Via dell'Artigianato, 7, 36030 Montecchio Precalcino, Vicenza, Italy

Product name: **PALFIQUE ESTELITE**

This product name includes following 14 products, namely

"PALFIQUE ESTELITE PASTE SYRINGE",
"PALFIQUE ESTELITE PASTE PLT",
"PALFIQUE ESTELITE LV",
"ESTELITE SYRINGE",
"ESTELITE PLT",
"ESTELITE FLOW QUICK SYRINGE"
"ESTELITE Σ QUICK SYRINGE",
"ESTELITE Σ QUICK PLT",
"ESTELITE FLOW QUICK High Flow SYRINGE",
"ESTELITE POSTERIOR"
"ESTELITE FLOW QUICK PLT"
"ESTELITE FLOW QUICK High Flow PLT".
"ESTELITE ASTERIA SYRINGE"
"ESTELITE COLOR"

(See attached sheet 1 for detail.)

Reference No.: PE01

Classification (MDD, AnnexIX): Class IIa

First Shipment Date: 13 November 1997
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 0120
SGS United Kingdom Ltd

Address: 202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK

Certificate: JP12/040317 (Annex II MDD)

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

Date: 18 September, 2014

Signature



Makoto Sakamoto
Executive Managing Director

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
PALFIQUE ESTELITE PASTE SET (syringe)	370807	13 November 1997
PALFIQUE ESTELITE PASTE INTRO KIT (syringe)	015E61	27 June 2011

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
PALFIQUE ESTELITE PASTE (syringe)	A1	42207	13 November 1997
	A2	04507	13 November 1997
	A3	15607 and 158Y7	13 November 1997
	A3.5	13767	13 November 1997
	Incisal	E80231E	13 November 1997
	B2	66137	13 November 1997
	B3	62507	13 November 1997
	B4	56507	13 November 1997
	C1	E30141E	13 November 1997
	C2	321Y6	13 November 1997
	C3	76266	13 November 1997
	Cervical	E90131E	13 November 1997
	OA1	E20141E	13 November 1997
	OA2	E10141E	13 November 1997
PALFIQUE ESTELITE PASTE Mini (syringe)	OA3	011E61	27 June 2011
	OA2 ¹⁾	-	-
PALFIQUE ESTELITE PASTE (PLT)	A1	A10281E	9 August 2001
	A2	A20481E	9 August 2001
	A3	A30381E	9 August 2001
	A3.5	A50381E	9 August 2001
	Incisal	IN0281E	9 August 2001
	B2	B20181E	9 August 2001
	B3	B30181E	9 August 2001
	B4	YB401Y1	9 August 2001
	C1	C10181E	9 August 2001
	C2	C20181E	9 August 2001
	C3	C30181E	9 August 2001
	Cervical	CE0281E	9 August 2001
	OA1	010181E	9 August 2001
	OA2	020181E	9 August 2001

		First Lot Number in EU market	First shipment date
PALFIQUE ESTELITE LV (High-Flow)	A1	30361E	9 August 2001
	A2	10461E	9 August 2001
	A3	21461E	9 August 2001
PALFIQUE ESTELITE LV (Low-Flow)	A1	70361E	9 August 2001
	A2	50571E	9 August 2001
	A3	61461E	9 August 2001
PALFIQUE ESTELITE LV (Medium-Flow)	A1	X10443	31 March 2003
	A2	20933	31 March 2003
	A3	31133	31 March 2003
	A3.5	X50343	31 March 2003

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
ESTELITE Σ SYRINGE $\times 4$	EM101Y4S	22 November 2004
ESTELITE Σ SYRINGE introductory kit	EM401Y4S	22 November 2004
ESTELITE Σ PLT introductory kit	EM501Y4	22 November 2004
ESTELITE Σ PLT mini kit	EM001Z7	21 December 2007
ESTELITE Σ system kit	YS50118	21 January 2008

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE Σ SYRINGE	A1	EE5011Y4S	22 November 2004
	A2	EE401104S	21 October 2004
	A3	EE60104S	21 October 2004
	A3.5	EE8011Y4S	22 November 2004
	Incisal	EW4521Y4S	22 November 2004
	B1	EW653Y4S	22 November 2004
	B2	EW60204S	21 October 2004
	B3	EW702Y4S	22 November 2004
	B4	EW5011Y4S	22 November 2004
	C1	EE0511Y4S	22 November 2004
	C2	EW8021Y4S	22 November 2004
	C3	EW901BY4S	22 November 2004
	Cervical	EE0011Y4S	22 November 2004
	BW	EW551Y4S	22 November 2004
	OA1	EW7521Y4S	22 November 2004
	OA2	EW8521Y4S	22 November 2004
	OA3	EW952104S	21 October 2004
	OB3	EW3521Y4S	22 November 2004
ESTELITE Σ PLT	A1	ESA103Z4	6 January 2005
	A2	ESA203Z4	21 December 2004
	A3	ESA30104	21 October 2004
	A3.5	ESA502Z4	21 December 2004
	Incisal	ESIN02Z4	21 December 2004
	B1	ESB103Z4	21 December 2004
	B2	ESB202Z4	21 December 2004
	B3	ESB302Z4	21 December 2004
	B4	ESB402Z4	21 December 2004
	C1	ESC102Z4	21 December 2004
	C2	ESC202Z4	21 December 2004
	C3	ESC302Z4	21 December 2004
	Cervical	ESCE02Z4	21 December 2004
	BW	ESBW04Z4	6 January 2005
	OA1	ESOA102Z4	21 December 2004
	OA2	ESOA202Z4	21 December 2004
	OA3	ESOA304Z4	13 January 2005
	OB3	ESOB304Z4	13 January 2005

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
ESTELITE FLOW QUICK SYRINGE ASSORTMENT (1mL) (ESTELITE FLOW QUICK 3 Syringe kit (1mL))	EL70125	21 December 2005
ESTELITE FLOW QUICK SYRINGE ASSORTMENT (2mL) (ESTELITE FLOW QUICK 3 Syringe kit (2mL))	001EZ9	25 December 2009

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE FLOW QUICK SYRINGE(1mL)	A1	EE50195	2 September 2005
	A2	EE40195	2 September 2005
	A3	EE60295	2 September 2005
	A3.5	EE80195	2 September 2005
	Incisal	EW45195	2 September 2005
	B1	EW65195	2 September 2005
	B2	EW60195	2 September 2005
	B3	EW70195	2 September 2005
	B4	EW50195	2 September 2005
	C1	EW05195	2 September 2005
	C2	EW80195	2 September 2005
	C3	EW90195	2 September 2005
	Cervical	EE00195	2 September 2005
	BW	EW551195	2 September 2005
	OA1	EW751195	2 September 2005
	OA2	EW851195	2 September 2005
OA3	EW951195	2 September 2005	
ESTELITE FLOW QUICK SYRINGE TIP × 50		X95	2 September 2005
ESTELITE FLOW QUICK SYRINGE(2mL)	A1	001EZ9	25 December 2009
	A2	001EZ9	25 December 2009
	A3	001EZ9	25 December 2009
	A3.5	001EZ9	25 December 2009
	A4(Cerv.)	001EZ9	25 December 2009
	B1	001EZ9	25 December 2009
	B2	001EZ9	25 December 2009
	B3	001EZ9	25 December 2009
	B4	001EZ9	25 December 2009
	C1	001EZ9	25 December 2009
	C2	001EZ9	25 December 2009
	C3	001EZ9	25 December 2009
	OA1	001EZ9	25 December 2009
	OA2	001EZ9	25 December 2009
	OA3	001EZ9	25 December 2009
CE(Inc.)	002EZ9	25 December 2009	
BW	001EZ9	25 December 2009	
ESTELITE FLOW QUICK SYRINGE Mini (0.5mL)	A2	001E70	26 July 2010
	A3	001E90	27 September 2010

First lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE FLOW QUICK PLT	A1	001E51	25 May 2011
	A2	001E41	20 April 2011
	A3	001E41	20 April 2011
	A3.5	001E41	20 April 2011
	Incisal	001E51	25 May 2011
	B1	001E51	25 May 2011
	B2	001E51	25 May 2011
	B3	001E51	25 May 2011
	B4	001E51	25 May 2011
	C1	001E51	25 May 2011
	C2	001E51	25 May 2011
	C3	001E51	25 May 2011
	Cervical	001E51	25 May 2011
	BW	001E51	25 May 2011
	OA1	001E51	25 May 2011
	OA2	001E41	20 April 2011
OA3	001E51	25 May 2011	

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
ESTELITE Σ QUICK 3 Syringe kit	001E78	22 July 2008
ESTELITE Σ QUICK SYRINGE introductory kit	001EY8	21 November 2008
ESTELITE Σ QUICK PLT introductory kit	001E78	22 July 2008
ESTELITE Σ QUICK PLT mini kit	001E78	22 July 2008
ESTELITE Σ QUICK SYRINGE system kit	001E78	22 July 2008
ESTELITE Σ QUICK PLT system kit	001E41	20 April 2011
ESTELITE Σ QUICK SYRINGE Promo kit	016E01	25 October 2011
ESTELITE Σ QUICK SYRINGE SYSTEM KIT II ¹⁾	-	-
ESTELITE Σ QUICK SYRINGE INTRO KIT II ¹⁾	-	-
ESTELITE Σ QUICK PLT INTRO KIT II ¹⁾	-	-

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

Attached sheet 1-7

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE Σ QUICK SYRINGE	A1	001E78	22 July 2008
	A2	001E78	22 July 2008
	A3	001E78	22 July 2008
	A3.5	001E78	22 July 2008
	A4	001E78	22 July 2008
	A5	001E78	22 July 2008
	B1	001E78	22 July 2008
	B2	001E78	22 July 2008
	B3	001E78	22 July 2008
	B4	001E78	22 July 2008
	C1	001E78	22 July 2008
	C2	001E78	22 July 2008
	C3	001E78	22 July 2008
	OA1	001E78	22 July 2008
	OA2	001E78	22 July 2008
	OA3	001E78	22 July 2008
	OPA2	001E78	22 July 2008
	BW	001E78	22 July 2008
	WE	001E78	22 July 2008
	CE	001E78	22 July 2008
ESTELITE Σ QUICK SYRINGE Mini	A2	001E78	21 August 2008
	A3	001E99	10 September 2009
ESTELITE Σ QUICK PLT	A1	001E78	22 July 2008
	A2	001E78	22 July 2008
	A3	001E78	22 July 2008
	A3.5	001E78	22 July 2008
	A4	001E78	22 July 2008
	A5	001E78	22 July 2008
	B1	001E78	22 July 2008
	B2	001E78	22 July 2008
	B3	001E78	22 July 2008
	B4	001E78	22 July 2008
	C1	001E78	22 July 2008
	C2	001E78	22 July 2008
	C3	001E78	22 July 2008
	OA1	001E78	22 July 2008
	OA2	001E78	22 July 2008
	OA3	001E78	22 July 2008
	OPA2	001E78	22 July 2008
	BW	001E78	22 July 2008
	WE	001E78	22 July 2008
	CE	001E78	22 July 2008

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE FLOW QUICK High Flow SYRINGE	A1	001E79	27 July, 2009
	A2	001E79	27 July, 2009
	A3	001E79	27 July, 2009
	OPA2	001E79	27 July, 2009
ESTELITE FLOW QUICK High Flow SYRINGE Mini	A2	001E70	26 July, 2010
	A3	001E70	26 July, 2010
ESTELITE FLOW QUICK METAL SYRINGE TIP × 50		004EZ9	10 December, 2009
ESTELITE FLOW QUICK High Flow PLT	A1	001E61	10 June, 2011
	A2	001E61	10 June, 2011
	A3	001E61	10 June, 2011
	OPA2	001E61	10 June, 2011

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE POSTERIOR	PCE	001E79	27 July, 2009
	PA1	001E79	27 July, 2009
	PA2	001E79	27 July, 2009
	PA3	001E79	27 July, 2009

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
ESTELITE ASTERIA SYRINGE essential kit	001E13	25 January, 2013

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE ASTERIA SYRINGE	A1B	001E13	25 January, 2013
	A2B	001E13	25 January, 2013
	A3B	001E13	25 January, 2013
	A3.5B	001E13	25 January, 2013
	A4B	001E13	25 January, 2013
	B3B	001E13	25 January, 2013
	BL	001E13	25 January, 2013
	NE	001E13	25 January, 2013
	WE	001E13	25 January, 2013
	YE	001E13	25 January, 2013
	TE	001E13	25 January, 2013
	OcE	001E13	25 January, 2013

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
ESTELITE COLOR kit	001E23	13 February, 2013

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
ESTELITE COLOR	Clear	001E23	13 February, 2013
	White	001E23	13 February, 2013
	Blue	001E23	13 February, 2013
	Yellow	001E23	13 February, 2013
	Gray	001E23	13 February, 2013
	Ochre	001E23	13 February, 2013
	Dark Brown	001E23	13 February, 2013
	Red	001E23	13 February, 2013
	Lavender	001E23	13 February, 2013
	Pink Opaque	001E23	13 February, 2013
	High Chroma Opaque	001E23	13 February, 2013
	Medium Chroma Opaque	001E23	13 February, 2013
	Low Chroma Opaque	001E23	13 February, 2013

Standards applied to this product are listed below.

Standard	Published year
EN ISO 10993-1	2009
EN ISO 10993-3	2009
EN ISO 10993-5	2009
EN ISO 10993-10	2010
EN ISO 10993-11	2009
EN ISO 10993-12	2012
EN ISO 10993-18	2009
EN ISO 13485	2012
EN ISO 14971	2012
EN 980	2008
EN 1041	2008
EN 1641	2009
EN ISO 7405	2008
ISO 15223-1	2012
EN ISO 4049	2009