38-9, Taitou 1-chome, Taitou-ku, Tokyo 110-0016 JAPAN
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Manufacturer's Declaration to Regulation (EU) 2023/607

According to Regulation (EU)2017/745 (MDR) and regarding the transitional provisions Tokuyama Dental Corporation declares the amendments to Article 120 of the MDR, as amended by Regulation (EU) 2023/607 applies to the following device(s):

Manufacturer name:	Tokuyama Dental Corporation
Manufacturer address and contact details:	38-9, Taitou 1-chome Taitou-ku Tokyo 110-0016 Japan
Single Registration Number (SRN) (if available):	JP-MF-000033625

Authorised Representative name	Tokuyama Dental Italy S.r.l
Authorised Representative address and contact details	Via Chizzalunga, 1 36066 Sandrigo, Vicenza Italy
Single Registration Number (SRN)	IT-AR-000021265

Notified body name (if applicable)	■ See attached schedule
Notified body number (if applicable)	■ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	■ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	■ See attached schedule
End date of extended validity/transition period	■ See attached schedule

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[1]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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■ Expired/expires *after* 20 March 2023:

■ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

■ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Tokuyama Dental Corporation

Masatsugu Kusano

Name: Masatsugu Kusano

Title: Factory Manager

Date: 12 January 2024

Place: Tokyo, Japan

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
PALFIQUE ESTELITE SYRINGE Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE Σ QUICK SYRINGE Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	

[2] As indicated on the Directive Certificate prior to the extension of the validity.

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Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
ESTELITE Σ QUICK PLT Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE POSTERIOR Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE ASTERIA SYRINGE Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE ASTERIA PLT Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	

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Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
ESTELITE COLOR Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE BULK FILL Flow SYRINGE Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE BULK FILL Flow PLT Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTELITE UNIVERSAL FLOW SYRINGE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	

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Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
Group name: PALFIQUE ESTELITE						
ESTELITE UNIVERSAL FLOW PLT Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
OMNICHROMA BLOCKER SYRINGE Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
OMNICHROMA BLOCKER PLT Group name: PALFIQUE ESTELITE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	

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Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
OMNICHROMA SYRINGE Group name: OMNICHROMA	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
OMNICHROMA PLT Group name: OMNICHROMA	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
OMNICHROMA FLOW SYRINGE Group name: OMNICHROMA FLOW	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
OMNICHROMA BLOCKER FLOW SYRINGE	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	

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Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
Group name: OMNICHROMA FLOW						
OMNICHROMA FLOW BULK SYRINGE Group name: OMNICHROMA FLOW	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
TOKUYAMA BOND FORCE II Group name: ONE-UP BOND F	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
TOKUYAMA BOND FORCE II Pen Group name: ONE-UP BOND F	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	

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TOKUYAMA UNIVERSAL BOND II Group name: TOKUYAMA UNIVERSAL BOND II	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
TOKUYAMA EE-BOND Group name: TOKUYAMA EE-BOND	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
ESTECEM II PLUS Group name: ESTECEM II PLUS	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 8	31 December, 2028	
TOKUYAMA SHIELD FORCE PLUS	JP19/040508	24 May, 2024	SGS Belgium NV NB# 1639	Class IIa Rule 5 and 8	31 December, 2028	

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Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
Group name: Protective Sealant						