

*GMED certifies that the quality management system developed by*

**PULPDENT CORPORATION**

**80 Oakland Street**

**WATERTOWN, MA 02472 UNITED STATES**

**Facility identifier (REPs-generated) : F000685**

*for the activities*

**Conception, fabrication de dispositifs médicaux à usage professionnel dentaires - Cf. addendum**

*Design, manufacturing of medical devices for professional dental use - cf. addendum*

*performed on the location(s) of*

**Voir addendum- See addendum – 4 sites USA**

**has been audited and found to conform to the requirements of the international standard  
ISO 13485 : 2016 and following regulatory requirements**

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

**Début de validité / Effective date July 2nd, 2021 (included)**

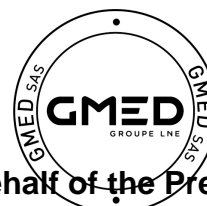
**Valable jusqu'au / Expiry date : July 27th, 2022 (included)**

**Etabli le / Issued on : July 2nd, 2021**



GMED is authorised under the Medical Devices Single Audit Program  
This certificate is issued according to the rules of GMED Certification  
The validity of this certificate can be verified on [www.gmed.fr](http://www.gmed.fr)

Modifie le certificat 34641-1



DocuSigned by:  
*Beatrice Lys*  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

**Ce certificat couvre les activités et les sites suivants :**

*This certificate covers the following activities and sites:*

**Conception, fabrication de dispositifs médicaux à usage professionnel dentaires, incluant les instruments et outils dentaires, les adhésifs dentaires, produits préparation des surfaces, produits pour comblement des puits et fissures, ciment verre ionomere et resine composite, produit pour le coiffage pulpaire, produits de comblement de fond de cavite et de canal radiculaire (non-médicinaux), pansements parodontaux, les matériaux pour couronnes et bridges temporaires et matériaux fluores et de reminéralisation**

*Design, manufacturing of medical devices for professional dental use including dental instruments and tools, dental adhesives, surface preparation materials, pit and fissure sealants, glass ionomer and resin composite materials, pulp capping materials, cavity liners and root canal sealant (non-medicated), periodontal dressings, temporary crown and bridge materials and cements, and fluoride and remineralization materials.*

**Puldent Corporation**

80 Oakland Street  
Watertown, MA 02472  
USA

**Fabrication de produits chimiques, emballage primaire, étiquetage, achats, contrôle de réception, réception, contrôle de la qualité, recherche et développement**

*Chemical products manufacturing, primary packaging, labeling, purchasing, incoming inspection, receiving, quality control, research and development*

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**Puldent Corporation**

73 Oakland Street  
Watertown, MA 02472  
USA

**Entreposage, personnalisation et réparation d'équipements de fabrication**

*Warehousing, customization and repair of manufacturing equipment*

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DocuSigned by:

*Beatrice Lys*  
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**On behalf of the President  
Béatrice LYS  
Technical Director**

**Puldent Corporation**

46 Acton Street  
Watertown, MA 02472  
USA

**Affaires cliniques, comptabilité, assurance de la qualité / affaires réglementaires, service à la clientèle, expédition**

Clinical affairs, accounting, Quality Assurance / Regulatory Affairs, customer service, shipping

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**Puldent Corporation**

300-304 Pleasant Street  
Watertown, MA 02472  
USA

**Assemblage de kits et étiquetage / Assembling kits and labeling**

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**4 sites / 4 sites**



DocuSigned by:

*Beatrice Lys*

EF33BDA9BAA04A3...

**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**