

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 28th, 2023 (included)

Valable jusqu'au / Expiry date : July 27th, 2026 (included)

Etabli le / Issued on : July 6th, 2023



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

Renouvelle le certificat 34641-3

DocuSigned by:
Béatrice Lys
EF33BDA9BA...
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 preparation 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 remineralisation

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
REPS Number: F000685

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

Puldent Corporation

73 Oakland Street
Watertown, MA 02472, USA
REPS Number: F000685

Entreposage, personnalisation et réparation d'équipements de fabrication

Warehousing, customization and repair of manufacturing equipment

DocuSigned by:

EF33BDA9BA094A3..

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

Puldent Corporation
46 Acton Street
Watertown, MA 02472, USA
REPS Number: F000685


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

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

Puldent Corporation
300-304 Pleasant Street
Watertown, MA 02472, USA
REPS Number: F000685

Assemblage de kits et étiquetage / Assembling kits and labeling

4 sites / 4 sites

DocuSigned by:

EF33BDA9BAA04A3*

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