DECLARATION of CONFORMITY

Manufacturer Name and Address:

Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472 USA
Tel: (617) 926-6666 Fax: (617) 926-6262

Product Ranges:

CLASS IIa DEVICES:

CAVITY LINERS
DENTAL ADHESIVES
GLASS IONOMER & RESIN COMPOSITE MATERIALS
PERIODONTAL DRESSINGS
PIT AND FISSURE SEALANTS
PULP CAPPING MATERIALS
ROOT CANAL SEALANTS (NON-MEDICATED)
SURFACE PREPARATION MATERIALS
TEMPORARY CROWN AND BRIDGE MATERIALS AND CEMENTS
FLUORIDE AND REMINERALIZATION MATERIALS

EC Declaration of Conformity:

I, the undersigned, hereby declare that the medical devices included in the product ranges specified above conform to the requirements of the Essential Requirements listed in Annex I of the EC Directive 93/42/EEC and to the requirements of the Pulpdent Quality Management System including all Quality Control Testing.

This Declaration is supported by:

EC Certificate No. 9101 rev. 11 issued by GMED S.A.S., effective 3 January 2020, for compliance with Directive 93/42/EEC, Annex II, Section 3;

Certificate of Registration No. 34640 rev 0, issued by GMED S.A.S., effective 30 September 2018, for compliance with the requirements of ISO 13485:2016;

Certificate of Registration No. 34641-0, issued by G-MED S.A.S., effective 30 September 2018, for compliance with the requirements of Australian TGA Regulations, 2002, Schedule 3 Part 1; Canadian Medical Devices Regulations, Part 1, SOR 98/282; Japanese MHLW MO 169 and the PMD Act; and United States 21 CFR 820, 803, 806, and 807 subparts A through D.

Signed: Marjorie Coté **Date:** 28 February 2020

Marjorie Coté
Director of Quality Assurance and Regulatory Affairs, Pulpdent Corporation

***Pulpdent* Notified Body:**

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