

## DECLARATION OF LOU FIORINI

I, Lou Fiorini, declare as follows:

1. I am the Director of Operations at Innovative Test Solutions, Inc. (“ITS”), an ISO 17025:2005 accredited, mechanical testing laboratory located in Schenectady, New York.
2. I have a Bachelor’s degree in Mechanical Engineering from SUNY Institute of Technology. I have approximately 18 years of work experience in the field of mechanical testing, including approximately 12 years of experience overseeing mechanical testing projects.
3. Patterson Belknap Webb & Tyler LLP (“PBWT”) retained ITS to perform heat treatments on certain shanks of nickel-titanium endodontic files, followed by stiffness testing of the shanks in accordance with ISO 3630-1:2008, Section 7.5. I designed the test apparatus, and oversaw the heat treatments, stiffness testing, and preparation of a report that summarizes the heat treatment cycles, test apparatus, test procedure, and results. A copy of that report, entitled “ISO 3630-1, Section 7.5 Stiffness Testing,” and identified as “Test Report ITS – 16141.02,” is attached to this declaration as Exhibit A. Based on my personal knowledge, the report was prepared at the time the testing was conducted, and in the course of the regularly-conducted business of ITS. Further, the information contained in the report is true and accurate.

4. In May 2016, ITS received from PBWT five plastic containers, each containing six nickel-titanium endodontic files. The containers were in their original, unopened packaging, which indicated the files were ProFile® brand, and of size 20, .04 taper, and 25 mm length. Each file consisted of a nickel-titanium shank portion and a handle. Prior to heat treatment, the handles of the files were removed at the point at which they were attached to the shanks.

5. ITS heat treated the shanks at the following times and temperatures:

| <b>Number of Shanks</b> | <b>Temperature</b>          | <b>Time</b> |
|-------------------------|-----------------------------|-------------|
| 2                       | Control (no heat treatment) |             |
| 2                       | 40° C                       | 75 minutes  |
| 2                       | 40° C                       | 2 hours     |
| 2                       | 40° C                       | 4 hours     |
| 2                       | 40° C                       | 8 hours     |
| 2                       | 40° C                       | 12 hours    |
| 2                       | 40° C                       | 24 hours    |
| 2                       | 40° C                       | 28 hours    |
| 2                       | 300° C                      | 24 hours    |
| 2                       | 300° C                      | 28 hours    |

6. All of the heat treatments were performed by placing the shanks in an air atmosphere in an industrial oven that was maintained at the indicated temperature. After being treated in the furnace for the indicated times, the shanks were removed and allowed to cool at room temperature.

7. Thereafter, and as mentioned above, the heat-treated shanks were subjected to stiffness testing in accordance with ISO 3630-1:2008, Section 7.5; the

test materials, equipment, techniques, and results are summarized in the report attached as Exhibit A.

I declare under penalty of perjury that the following is true and correct.

Executed on August 4, 2016



Lou Fiorini

# EXHIBIT A



## **ISO 3630-1, Section 7.5 - Stiffness Testing**

**Author: James Dutelle**

**Test Report ITS – 16141.02**

**Wednesday, August 03, 2016**

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