

# MANI, INC.

8-3 KIYOHARA INDUSTRIAL PARK, UTSUNOMIYA, TOCHIGI, 321-3231 JAPAN  
Dental Sec./PHONE:81-28-667-8592 TELEFAX:81-28-667-8593

## Declaration of Conformity

MANUFACTURER'S NAME : MANI, INC.

ADDRESS : 8-3 Kiyohara Industrial Park, Utsunomiya  
Tochigi, 321-3231, Japan

EU REPRESENTATIVE'S NAME : Obelis s.a.

ADDRESS : Bd. General Wahis 53, 1030 Brussels  
Belgium

### DESIGNATION OF THE MATERIAL :

Dental Rotary Instruments  
Dental Endodontic Instruments  
Dental Pins and Posts

### DESCRIPTION

|                       |            |                            |            |
|-----------------------|------------|----------------------------|------------|
| REAMERS               | CLASS I    | PASTE CARRIERS             | CLASS II a |
| K-FILES               | CLASS I    | ULTRASONIC FILES           | CLASS II a |
| H-FILES               | CLASS I    | SUPER FILES                | CLASS II a |
| MEDIUM REAMERS        | CLASS I    | ENGINE REAMERS             | CLASS II a |
| MEDIUM K-FILES        | CLASS I    | ENGINE H-FILES             | CLASS II a |
| MEDIUM H-FILES        | CLASS I    | NRT FILES                  | CLASS II a |
| MEDIUM FLEXILE FILES  | CLASS I    | PEESO REAMERS              | CLASS II a |
| FLEXILE FILES         | CLASS I    | GATES DRILLS               | CLASS II a |
| SEC O-FILES K         | CLASS I    | MI STAINLESS BURS          | CLASS II a |
| SEC O-FILES H         | CLASS I    | DIAMOND ROTARY INSTRUMENTS | CLASS II a |
| FLARE FILES           | CLASS I    | CARBIDE BURS               | CLASS II a |
| RT FILES              | CLASS I    |                            |            |
| D FINDERS             | CLASS I    |                            |            |
| FINGER SPREADERS      | CLASS I    |                            |            |
| FLARE FINGER SPREADER | CLASS I    |                            |            |
| FINGER PLUGGERS       | CLASS I    |                            |            |
| BARBED BROACHES       | CLASS I    |                            |            |
| SMOOTH BROACHES       | CLASS I    |                            |            |
| SHORT BARBED BROACHES | CLASS I    |                            |            |
| SUTURES               | CLASS II a |                            |            |
| EG POST               | CLASS II a |                            |            |

THE UNDERSIGNED DECLARED THAT THE MATERIAL SPECIFIED IS ADAPTED TO EC DIRECTIVE

93 / 42 / EEC Annex II, excluding Section 4, Full Quality Assurance System Medical Devices  
Registration No.: HD 60097627 0001 / Report No.: 12022703 001

DATE & PLACE Utsunomiya, Tochigi, JAPAN June. 25, 2018

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AKIHIRO SHINOZAKI, General Manager