

## EC Declaration of Conformity

Doc No : DC-026

Rev.No : 7

**Manufacturer :**

DiaDent Group International  
16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu,  
Cheongju-si, Chungcheongbuk-do,  
28161, Republic of Korea

**Authorized Representative :**

DiaDent Europe B.V.  
Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

### STAINLESS STEEL HAND FILES

(Reamers, K-Files, H-Files)

GMDN : 31878

meet the provisions of The Medical Devices Directive 93/42/EEC amended by 2007/47/EC which apply to them.

The medical device has been assigned to Class I (Rule 5) according to Annex IX of  
the Medical Devices Directive 93/42/EEC amended by 2007/47/EC.

The product concerned has been designed and manufactured under a quality management system according to Annex VII  
of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of  
the Medical Devices Directive 93/42/EEC amended by 2007/47/EC

The above mentioned declaration of conformity is exclusively under the responsibility of

### DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si Chungcheongbuk-do, 28161, Republic of Korea

2020-06-01

Date

Signature

**DiaDent**<sup>®</sup>**DiaDent Group International**

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