

EC Declaration of Conformity

Doc No : DC-017

Rev.No : -5-

*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

Nickel Titanium Rotary Files (HELIX)
(including system components and accessories)
UMDNS-Code: 11-701

meet the provisions of Directive 93/42/EEC and 2007/47/EEC which apply to them.

The medical device has been assigned to class II (Rule 6) according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.



Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 60102395 0001
Issue date: 2016-01-15
Expiry date: 2020-06-01

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

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

2016.01.15

Place, date

signature,

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