

# EC Declaration of Conformity

Doc No : DC-036  
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*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

## HELIX ORGANIZER

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

The medical device has been assigned to class I (Rule 1) 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 VII of Directive 93/42/EEC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII 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



2016.03.22

Place, date

signature,