



Gendex Dental Systems  
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**EC Declaration of Conformity**

**A. Name/Description of product:**

GXS-700 Intraoral Digital Sensor

**Class: IIa**

**B. Reference Standards under which conformity is declared:**

IEC 60601-1:1988 Ed. 2; A1:1991 + A2:1995  
IEC 60601-1-1:2000, Second Edition  
IEC 60601-1-2:2007,  
CAN/CSA C22.2 No 601.1-M90 (1990), 2<sup>nd</sup> Edition  
UL60601-1 (2003) Revision 4.26.2006  
EN 60601-1:1990, Ed 2, A1:1991 + A2:1995  
ISO 14971:2007

**C. Gendex Dental System declares that the products described herein meet all the applicable Essential Requirements of the EC Medical Device Directive 93/42/EEC in Annex I. For Class IIa products described herein, the product is manufactured, inspected, tested, and released in accordance with the approved quality assurance system established in accordance with ISO 13485 and Annex II of the EC Medical Device Directive under the supervision of the British Standards Institution, a Notified Body carrying the Notified Body No. 0086.**

Signed: \_\_\_\_\_

Mehul Patel, Vice President - Engineering

Date: \_\_\_\_\_

5/26/10