



American Eagle Instruments® Inc.

better DENTISTRY *by* DESIGN™

EC Declaration of Conformity

Manufacturer:

American Eagle Instruments, Inc
6575 Butler Creek Road, Missoula, Montana, 59808, United States of America
Phone: (800) 551-5172 – Fax: (406) 549-7452

Certification Body:

AMTAC Certification Services Limited
Davy Avenue, Knowlhill, Milton Keynes, MK5 8NL, U.K.
Phone: +44 (0) 1908 857 750

Authorized European Representative:

G. Lawrence
31 Windrush Ave., Langley, Berkshire, SL3 8EA, U.K.
Phone: +44 (0) 1753 770 010

Equipment Model Designation(s) and Description(s):

Product Families	Description
Operative Dental Instruments	Used in restorative capacities
Composite Dental Instruments	Used in restoration "filling" capacities
Diagnostic Dental Instruments	Used for analysis and examination capacities
Hygiene Dental Instruments	Used for Perio-related capacities
XP Technology® Dental Instruments	Used for Perio-related capacities
Surgical Dental Instruments	Used in Oral and related operations (i.e. extractions)
Dental Cassettes	Accessory to Class I instruments
Dental Cleaning Solutions and Lubricants	Accessory to Class I instruments

All Class I instruments manufactured from March 1998 and thereafter are valid under this declaration

Equipment Designated Class by Definition: (Class I) as per the Medical Devices Directive of Council Directive 93/42/EEC as amended by 2007/47/EC and all harmonized standards thus including ISO 13485:2003 and ISO 9001:2008.

CE
The necessary pre-requisites for placing the CE mark on the above mentioned product and the marketing of them in all Member States of the European Union have thus been fulfilled.
Signed this <u>15</u> day of <u>March</u> 2012
By: <u>Jerry Schreiber</u>
Title: <u>Vice President</u>

COW-FO33
Rev 001