

DECLARATION OF CONFORMITY

Manufacturer:	Gestenco International AB P O Box 24067 SE 400 22 Gothenburg SWEDEN
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Device Information

Product name:	Smartbond
Trademark:	
Type:	Dental bonding materials
Classification rule number:	Rule no 5
GMDN:	31750

Device Classification as per Medical Device Directive 93/42/EEC	Class IIa
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Product Identification Number (Medical Products Agency, Sweden)	
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Annex II Notified Body:	Nordic Dental Certification, Identification No. 0510
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EC Declaration of Conformity:	Full quality assurance system
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Ta bort denna rad vid utskrift: fyll i rätt "Class" nedan

Declaration:	Gestenco International AB hereby declares that the medical device specified above to which this declaration relates is a Class IIa device following the provisions of the Medical Device Directive 93/42/EEC
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Declaration Based On:	SS-EN ISO 9001/ EN ISO 13485 Quality System
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Declaration of Conformance Issued By:	Gestenco International AB Box 24067 SE 400 22 Gothenburg SWEDEN
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Prepared By:

Goran Steen
Managing Director


(Signature)

May 11, 2010

(Date)