

**DECLARATION OF CONFORMITY**

<b>Manufacturer:</b>	Gestenco International AB P O Box 24067 SE 400 22 Göteborg SWEDEN
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**Device Information**

<b>Product name:</b>	<b>BB-00-01 Bite-Bumper</b>
<b>Trademark:</b>	Bite-Bumper
<b>Type:</b>	Plastic orthodontic device for open and deep bites
<b>Classification rule number:</b>	Rule no 5
<b>GMDN:</b>	41059

<b>Device Classification as per Medical Device Directive 93/42/EEC</b>	Class IIa
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<b>Product Identification Number (Medical Products Agency):</b>	
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<b>Annex II Notified Body:</b>	Nemko AS, Identification No. 0470
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<b>EC Declaration of Conformity:</b>	Full quality assurance system
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<b>Declaration:</b>	Gestenco International AB hereby declares that the medical device specified above to which this declaration relates is a <b>Class IIa</b> device in conformity with the essential requirements of the Medical Device Directive 93/42/EEC
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<b>Declaration Based On:</b>	SS-EN ISO 9001/ EN ISO 13485 Quality System
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<b>Declaration of Conformance Issued By:</b>	Gestenco International AB Box 24067 SE 400 22 GÖTEBORG SWEDEN
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**Prepared By:**Göran Steen  
(Managing director)  
(Signature)

November 28, 2011

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(Date)