

**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>Imagine Lip-Retractor part number:</b> LR-00-01 (adult size) LR-00-02 (child size)
<b>Trademark:</b>	Lip-retractor
<b>Type:</b>	Lip retractor
<b>GMDN:</b>	13380

<b>Device Classification as per Medical Device Directive 93/42/EEC</b>	Class Ia
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<b>Product Identification Number (Medical Products Agency):</b>	92569 (Lip-Retractor adult size) 92570 (Lip-Retractor child size)
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<b>Annex II Notified Body:</b>	Nemko AS, 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 Ia</b> device following the provisions 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)

December 09, 2011

  
(Signature)\_\_\_\_\_  
(Date)