

**DECLARATION OF CONFORMITY**

<b>Manufacturer:</b>	Gestenco International AB P O Box 24067 SE 400 22 Gothenburg SWEDEN
----------------------	--

**Device Information**

<b>Product name:</b>	CR-00-01, Check Retractor
<b>Trademark:</b>	Cheek Retractor
<b>Type:</b>	Dental protector
<b>Classification rule number:</b>	Rule no 5
<b>GMDN:</b>	13380

<b>Device Classification as per Medical Device Directive 93/42/EEC</b>	Class I
--	---------

<b>Product Identification Number (Medical Products Agency, Sweden)</b>	59677
--	-------

<b>Annex II Notified Body:</b>	Nemko AS no 0470
--------------------------------	------------------

<b>EC Declaration of Conformity:</b>	Full quality assurance system
--------------------------------------	-------------------------------

*Ta bort denna rad vid utskrift: fyll i rätt "Class" nedan*

<b>Declaration:</b>	Gestenco International AB hereby declares that the medical device specified above to which this declaration relates is a <b>Class I</b> device following the provisions of the Medical Device Directive 93/42/EEC
---------------------	---

<b>Declaration Based On:</b>	SS-EN ISO 9001/ EN ISO 13485 Quality System
------------------------------	---

<b>Declaration of Conformance Issued By:</b>	Gestenco International AB Box 24067 SE 400 22 Gothenburg SWEDEN
--	--

**Prepared By:**

  
(Signature)

November 23, 2011

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