


# Declaration Of Conformity

Manufacturer:	CMS Dental A/S Ragnagade 7 2100 Copenhagen - Denmark																														
Conformity assessment procedure:	Annex II of the Medical Devices Directive 93/42/EEC																														
Certificate(s):	<p>EC Certificate EU1101405            Issue date: 2012-05-23            Valid until: 2016-02-01            Issued by: NEMKO 0470</p> <p>Quality Management System – medical devices            ISO 13485:2003            Certificate No.: 908167            Issue date: 2013-12-21            Valid until: 2016-12-21            Issued by: DNV Nemko Presafe AS</p>																														
Product Identification and names(s):	<p style="text-align: center;"><b>Soft-Core Regular – Class IIA – GMDN CODE: 31872</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Item no</th> <th style="text-align: left;">Description</th> <th style="text-align: left;">Classification</th> </tr> </thead> <tbody> <tr> <td>OSR20/20</td> <td>20 x One-Step Obturator #20</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/25</td> <td>20 x One-Step Obturator #25</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/30</td> <td>20 x One-Step Obturator #30</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/35</td> <td>20 x One-Step Obturator #35</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/40</td> <td>20 x One-Step Obturator #40</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/50</td> <td>20 x One-Step Obturator #50</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/60</td> <td>20 x One-Step Obturator #60</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/20-60</td> <td>20 x One-Step Obturator #20-30</td> <td>Class IIA</td> </tr> <tr> <td>OSR20/35-60</td> <td>20 x One-Step Obturator #20-30</td> <td>Class IIA</td> </tr> </tbody> </table>	Item no	Description	Classification	OSR20/20	20 x One-Step Obturator #20	Class IIA	OSR20/25	20 x One-Step Obturator #25	Class IIA	OSR20/30	20 x One-Step Obturator #30	Class IIA	OSR20/35	20 x One-Step Obturator #35	Class IIA	OSR20/40	20 x One-Step Obturator #40	Class IIA	OSR20/50	20 x One-Step Obturator #50	Class IIA	OSR20/60	20 x One-Step Obturator #60	Class IIA	OSR20/20-60	20 x One-Step Obturator #20-30	Class IIA	OSR20/35-60	20 x One-Step Obturator #20-30	Class IIA
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Serial numbers covered by this declaration:	All																														
<p>We, the manufacturer, hereby declare that the above mentioned products comply with the European Medical Device Directive 93/42/EEC and it's relevant transposition into national laws of the member states into which we place the device.</p>																															
Copenhagen	December 21, 2013																														
Name and authority	Jimmie Kert/Quality Manager																														
Signature																															



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