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CE DECLARATION OF CONFORMITY		Certificate N° 13/BE/2986-0-REV 0																											
In accordance with the Directive 93/42/EEC on medical devices, annex II (excluding Section 4) and its latest amendment 2007/47/EEC																													
Manufacturer	Name	SURGICAL INSTRUMENTS BELGIUM S.A MEDSYS S.A.																											
	Address	Rue du Gaillard 3 B – 5030 Gembloux BELGIUM																											
<table border="1"> <thead> <tr> <th>Concerned products</th> <th>Technical file</th> <th>Revised on</th> <th>Class</th> <th>Rule</th> </tr> </thead> <tbody> <tr> <td>Sterile and non sterile electrosurgical electrode LEE</td> <td>EL8-001a</td> <td>02/05/2012</td> <td>IIb</td> <td>9</td> </tr> <tr> <td>Lap Loop (instrument and sterile electrodes)</td> <td>LL08-003</td> <td>03/11/2008</td> <td>IIb</td> <td>6</td> </tr> <tr> <td>Lap Stick (sterile remote control)</td> <td>LS8-002b</td> <td>02/09/2005</td> <td>I</td> <td>12</td> </tr> <tr> <td>Uterine manipulator</td> <td>MD8001a</td> <td>14/11/2008</td> <td>I</td> <td>6</td> </tr> </tbody> </table>					Concerned products	Technical file	Revised on	Class	Rule	Sterile and non sterile electrosurgical electrode LEE	EL8-001a	02/05/2012	IIb	9	Lap Loop (instrument and sterile electrodes)	LL08-003	03/11/2008	IIb	6	Lap Stick (sterile remote control)	LS8-002b	02/09/2005	I	12	Uterine manipulator	MD8001a	14/11/2008	I	6
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<p>This document certifies that the quality management system of the above mentioned manufacturer has been assessed and certified as meeting the requirements of Directive 93/42/EEC on medical devices, Annex II (excluding Section 4) and its latest amendment and meets the requirements for the above listed equipment.</p> <p>The approval is subject to the continuity of the maintenance of the quality management system in accordance with the requirements of the Directive 93/42/EEC. It will be controlled by interim audits, inspections and surveillance.</p> <p>The manufacturer is allowed to affix the CE marking with our identification number of Notified Body 0029, for equipment approved under the conditions laid down in the Directive.</p> <p style="text-align: center;">This approval is valid until 06/01/2018</p>																													
Date : 07/01/2013	Name : Ch. Leplat	Position	General Manager																										
Notified body identification number :	0029	Signature																											
Notified body stamp :	APRAGAZ Belgium Inspecting Authority																												
Notified body reference :	P8246/005																												