



ID-Nr. B-0001/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

General Medicine and ENT Instruments including accessory

Allgemeinmedizin und HNO Instrumente inklusive Zubehör

in the following configurations

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Otoscope	BETA 100	B-00*.11.52*
Otoscope	BETA 200	B-00*.11.500
Otoscope	K 100	B-00*.11.57* / B-245.10.118
Otoscope	K 180	B-00*.11.550
Otoscope	alpha+	D-00*.80.108
Otoscope	mini 2000	D-001.70.205
Otoscope	mini 3000	D-001.70.2**
Otoscope	mini 2000 F.O.	D-001.70.105
Otoscope	mini 3000 F.O.	D-001.70.1**
Operating Otoscope	-	B-00*.11.492
Reusable Tip	SANALON S black	B-000.11.107-.110
Reusable Tip	SANALON S blue	B-000.11.157-.160
Nasal Speculum	SANALON S	B-000.11.143
Disposable Tip	All-Spec	B-000.11.12*
Reusable Speculum	SANALON S	B-000.11.215-.220
Disposable Speculum	UniSpec	B-000.11.24* / B-000.11.237/8
Straight Laryngeal Mirror	-	B-00*.12.10*
Straight Laryngeal Mirror	mini 2000/3000	D-001.77.10*
Curved Laryngeal Mirror	-	B-00*.12.20*
Tongue Depressor	-	B-00*.12.30*
Tongue Depressor	alpha+/mini 2000	D-00*.74.100
Tongue Depressor	mini 3000	D-001.74.103
Fiberoptics Nasal Illuminator	-	B-00*.12.32*
Fiberoptics Nasal Illuminator	mini 2000	D-001.76.100
Fiberoptics Nasal Illuminator	mini 3000	D-001.76.101
Cliplamp	mini 1000	D-001.73.111
Cliplamp Head	mini 2000	D-001.73.120
Cliplamp Head	mini 3000	D-001.73.130
mini-c Cliplamp Head	mini-c	D-009.73.108
mini-c Cliplamp	mini-c Cliplamp	D-001.73.109
mini-c Cliplamp and Ear Light	-	D-000.73.106/5
Cliplamp	ClipLight	D-001.73.150
Cliplamp	mini 2000	D-001.73.129
Cliplamp	mini 3000	D-001.73.131
Combilamp	mini 2000	D-001.76.119
Combilamp	mini 3000	D-001.76.120
Combilamp without handle	mini 3000	D-001.76.101



ID-Nr. B-0001/01

<u>Name or Type of device</u>		<u>Article-/Catalog-Number</u>
Disposable Tongue Blades	-	B-000.11.304
Insufflation Bulb	-	B-000.11.240
Insufflation Bulb	-	D-000.80.102
Spreadable Nasal Speculum	-	B-000.11.231
Universal Speculum	-	B-000.11.239

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2012-01-16 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-01-16

Oliver Heine, BA
- President & CEO -