

## EC Declaration of Conformity

<b>Annex:</b>	Annex II (Excluding section 4) of the MDD (93/42/EEC), Full Quality Assurance System	
<b>Manufacturer's Name, Address:</b>	Teleflex Medical 2345 Waukegan Road Bannockburn, Illinois 60015 USA	
<b>Authorized Representative Address:</b>	TFX Medical Ltd. Stirling Road Cressex Business Park High Wycombe Buckinghamshire, HP 12 3 ST U.K.	
<b>Notified Body Name, Address:</b>	SGS United Kingdom, Ltd. Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS22 0WA, U.K. CE 0120	
<p>Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 and is in accordance with Annex I and Annex II (excluding section 4), and ISO 13485:2003, as implemented by the European Union's Medical Devices Regulations as verified by SGS:</p> <p>Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.</p> <p>Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.</p> <p>Teleflex Medical agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.</p> <p>Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.</p> <p>Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.</p> <p>Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.</p>		
<b>Product Name:</b>	Masks	
<b>Classification:</b>	Class IIa, Rule 5	
<b>EC Certificates No.:</b>	Canadian – ISO 13485: 2003 – CA03/2838 Europe – ISO 13485: 2003 – GB97/10878 Europe – 93/42/EEC Certificate – GB05/65510	
<b>Product Codes:</b>		CE mark as applied by SGS:
41053 Mask, Fixed Venture, Adult, 24%		September 6, 2005
41054 Mask, Fixed Venture, Adult, 28%		September 6, 2005
41055 Mask, Fixed Venture, Adult, 35%		September 6, 2005
41056 Mask, Fixed Venture, Adult, 40%		September 6, 2005
41057 Mask, Fixed Venture, Adult, 50%		September 6, 2005
41096 Mask Kit, Fixed Venturi, Paediatric w/Tubing		September 6, 2005
41098 Mask Kit, Fixed Venturi, Adult, w/Tubing		September 6, 2005
41072 Fixed Venturi Adaptor Set, 28%		September 6, 2005
41073 Fixed Venturi Adaptor Set, 40%		September 6, 2005
41088 Mask Multi-Vent, Adult		September 6, 2005
41089 Mask, Multi-Vent, Pediatric		September 6, 2005
1083 Mask, Adult, Aerosol, Elongated		September 6, 2005
41084 Mask, Adult, Aerosol		September 6, 2005
41085 Mask, Pediatric, Aerosol, Elongated		September 6, 2005
41035 Mask, Pediatric, Medium Concentration		September 6, 2005
41040 Mask, Adult, Medium Concentration		September 6, 2005
1041 Mask, Adult, Medium Concentration, Elongated		September 6, 2005
1041L Mask, Adult, Medium Concentration, Elongated		September 6, 2005
41042 Mask, Pediatric, Medium Concentration, Elongated		September 6, 2005

41042L Mask, Paediatric, Medium Concentration, Elongated	September 6, 2005
41049 Mask, Adult, Med Concen. Elongated - W/O Tubing	September 6, 2005
41050 Mask, Medium Concentration Elongated, Pediatric w/o Tubing	September 6, 2005
41050L Mask, Medium Concentration Elongated, Pediatric w/o Tubing	September 6, 2005
41051 Mask, Adult, Medium concentration, Elongated w/Starlumen Tubing	September 6, 2005
41052 Mask, Paediatric, Medium concentration, Elongated w/Starlumen Tubing	September 6, 2005
41067 Mask, Non-Rebreathing	September 6, 2005
41068 Mask, w/Safety Vent, Ear Loop Bands	September 6, 2005
41007 Mask, Adult, High concentration, elongated	September 6, 2005
41011 Mask, High Concen., Elongated, Pediatric	September 6, 2005
41058 Mask, Non-Rebreath w/Safety Vent, E Long, Pediatric	September 6, 2005
41058L Mask, Non-Rebreath w/Safety Vent, E Long, pediatric	September 6, 2005
41059 Mask, Non-Rebreathing w/Safety Vent, Elong, Adult	September 6, 2005
41059L Mask, Non-Rebreathing w/Safety Vent, Elong, Adult	September 6, 2005
41060 Mask, Non-Rebreathing w/o Safety Vent, Elongated, Adult	September 6, 2005
41069 Mask, Non-Rebreath w/Safety Vent, Elongated, Adult	September 6, 2005
41061 Mask, Three-in-one, Tubing	September 6, 2005
41062 Mask, Three-in-one, w/o Tubing	September 6, 2005
41063 Adult Mask, Three-in-one, Starlumen TBG w/STD Connectors	September 6, 2005
41064 Ped Mask, Three-in-one, Starlumen TBG w/STD Connectors	September 6, 2005
41075 Mask, Tracheostomy, Adult	September 6, 2005
41076 Mask, Tracheostomy, Pediatric	September 6, 2005
41095 Face Tent	September 6, 2005
41271 Air Cushion Mask, Neonate	September 6, 2005
41272 Air Cushion Mask, Infant	September 6, 2005
41273 Air Cushion Mask, Paediatric	September 6, 2005
41274 Air Cushion Mask, Small Adult	September 6, 2005
41275 Air Cushion Mask, Medium Adult	September 6, 2005
41276 Air Cushion Mask, Large Adult	September 6, 2005
41277 Air Cushion Mask, Neonate with Valve	September 6, 2005
41278 Air Cushion Mask, Infant with Valve	September 6, 2005
41279 Air Cushion Mask, Paediatric with Valve	September 6, 2005
41280 Air Cushion Mask, Small Adult with Valve	September 6, 2005
41281 Air Cushion Mask, Medium Adult with Valve	September 6, 2005
41282 Air Cushion Mask, Large Adult with Valve	September 6, 2005

5/15/2006

Date

Angela Tran, Regulatory Affairs Manager, International

*Angela Tran*  
Signature