

Annex:	Annex II (excluding section 4), Full Quality Assurance System
Manufacturer's Name, Address:	Teleflex Medical 2917 Weck Dr. Research Triangle Park, NC 27709 USA
Authorized Representative Address:	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath Ireland
Notified Body Name, Address:	SGS United Kingdom, Ltd. Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS22 0WA, U.K. CE 0120

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 II (excluding Section 4) and ISO 13485:2003, as implemented by the European Union's Medical Devices Regulations as verified by SGS:

Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.

Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

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.

Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.

Product Name: Masks

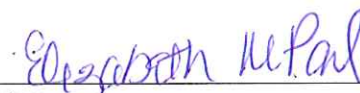
Classification: Class IIa Rule 2

EC Certificates No.: Canadian – ISO 13485:2003-US03/2838
European – ISO 13485:2003-US97/10878, Directive 93/42/EEC-US97/10879

Product Codes:	Product Description	CE Distribution Date:	GMDN Code
OXYGEN MASKS			
<u>Low Flow</u>			
41035	MASK,MED CONC,PED,INTL	September 6, 2005	35171
41040	MASK,MED CONC,ADULT,INTL	September 6, 2005	35171
1041	MASK,MEDIUM CONC,ELONG,ADULT	September 6, 2005	35171
1041L	MASK,MEDIUM CONCEN,ADULT ELONGATED	September 6, 2005	35171
1041B	MASK,MEDIUM CONC,ELONG,ADULT,BULK	September 6, 2005	35171
41042	MASK,MED CONC,ELONG,PED,INTL	September 6, 2005	35171
41042L	MASK,MEDIUM CONCEN,PEDIATRIC ELONGATED	September 6, 2005	35171
1049	MASK,MEDIUM CONC W/O TUBING,ELONG,ADULT	September 6, 2005	35171
1049B	MASK,1049 ADULT (BULK)	September 6, 2005	35171
41050	MASK,MED CONC,ELONG W/O TBG,PED,INTL	September 6, 2005	35171
41050L	MASK,MEDIUM CONCEN,W/O TBG PED ELONGATED	September 6, 2005	35171
41007	MASK,HIGH CONC,ADULT,INTL	September 6, 2005	35174
395406	INFANT MASK REBIRTH HIGH C	September 6, 2005	35174

395497	INFANT OXY HI-CON	September 6, 2005	35174
395498	Infant Mask Non-Rebth High ConC 50/BOX	September 6, 2005	35173
395407	INFANT OXY HI-CON	September 6, 2005	35174
395499	INFANT MASK MEDIUM CONCEN	September 6, 2005	35171
396218	INFANT MSK MED CONCT 7' T	September 6, 2005	35171
395826	INFANT MASK UNDER THE CHIN	September 6, 2005	35171
41058	MASK,NON-REBREATHING W/SAFETY VENT,ELONG	September 6, 2005	35173
41058L	MASK,NON-REBREATH,W/SFTY VENT,PED ELONG	September 6, 2005	35173
1059	MASK,NON-REBREATH W/SAFETY VENT,ELONGATE	September 6, 2005	35173
1059L	MASK,NON-REBREATHING,W/SAFETY VENT,ADULT	September 6, 2005	35173
41060	MASK,NON-REBREATHING W/O SFTY VENT,ELONG	September 6, 2005	35173
41069	MASK,NON-REBREATH W/SAFETY VENT,ELONG	September 6, 2005	35173
41061	MASK,THREE-IN-ONE,W/7' TUBING,INTL	September 6, 2005	35174
41063	MASK,THREE-IN-ONE,W/7' STAR LUMEN TUBING	September 6, 2005	35174
1389	OXYME FACE TENT	June 2008	35171
High Flow - Multi-Vent			
41088	MASK,MULTI-VENT,ADULT,INTL	September 6, 2005	35175
41089	MASK,MULTI-VENT,PEDIATRIC,INTL	September 6, 2005	35175
High Flow - Select-A-Vent			
41098	MASK KIT,FIXED VENTURI,ADULT,INTL	September 6, 2005	35175
41072	SELECT-A-VENT FIXED DILUTER AIR ENTRAINM	September 6, 2005	35175
AIR CUSHION MASKS, COLOR CODED			
41271	AIR CUSHION MASK,NEONATE,INTL	July 1, 2003	46232
41272	AIR CUSHION MASK,INFANT,INTL	July 1, 2003	46232
41273	AIR CUSHION MASK,PED/TODDLER,INTL	July 1, 2003	46232
41274	AIR CUSHION MASK,SMALL ADULT YOUTH,INTL	July 1, 2003	46232
41275	AIR CUSHION MASK,MED ADULT,INTL	July 1, 2003	46232
41276	AIR CUSHION MASK,LARGE ADULT,INTL	July 1, 2003	46232
41277	AIR CUSHION MASK W/VALVE,NEONATE,INTL	July 1, 2003	46232
41278	AIR CUSHION MASK W/VALVE,INFANT,INTL	July 1, 2003	46232
41279	AIR CUSHION MASK W/VALVE,PED/TODLR,INTL	July 1, 2003	46232
41280	AIR CUSHION MASK W/VALVE,SM ADULT,INTL	July 1, 2003	46232
41281	AIR CUSHION MASK W/VALVE,MED ADULT,INTL	July 1, 2003	46232
41282	AIR CUSHION MASK W/VALVE,LRG ADULT,INTL	July 1, 2003	46232
AEROSOL MASKS			
1083	MASK,AEROSOL,ELONGATED,ADULT	September 6, 2005	35142
1083B	MASK,AEROSOL,ELONGATED,ADULT (Bulk)	September 6, 2005	35142
41085	MASK,AEROSOL,ELONG,PED,INTL	September 6, 2005	35142
41095	FACE TENT,INTL	September 6, 2005	35142
1075	MASK,TRACHEOSTOMY,ADULT	September 6, 2005	35142
41076	MASK, TRACHEOSTOMY, PED, INTL	September 6, 2005	35142

Elizabeth Paul, Director, RA/QE Anesthesia / Respiratory
Name and Title


Signature

02 Aug 2014
Date