CE 0123	**EC Declaration of Conformity** *EG Konformitätserklärung*	Date / *Datum* 2020-06-04
	European Directive 93/42/EEC, Annex II **European Directive 2011/65/EC** *Europäische Richtlinie 93/42/EWG, Anhang II* *Europäische Richtlinie 2011/65/EG*	Document ID / *Dokument Nr.* MD101-035-2006-021-0

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hereby declares under its sole responsibility that the / erklärt hiermit in alleiniger Verantwortung, dass

Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*	Device Class	UMDNS Code / GMDN Code
Atlan	Anesthesia Workstation	IIb	10-134 / 37710

meets the provisions of the following European Directives:
- 93/42/EEC on medical devices. An examination of the quality management system has been carried out following Annex II.3 of the directive by the Notified Body TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, EC No. 0123. The quality management system also complies to EN ISO 9001 and EN ISO 13485.
- 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
This declaration is effective for products placed on the market as of the date of issue. Any modifications of the medical device not authorized by Draeger will invalidate this declaration.

mit den Bestimmungen der folgenden europäischen Richtlinien übereinstimmt:
-93/42/EWG über Medizinprodukte Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang II.3 der Richtlinie beschrieben, wurde durch die Benannte Stelle TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 München, EU Kennnummer 0123, *vorgenommen. Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.*
-2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten.
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Draeger autorisierte Modifikation an dem Medizinprodukt führt zur Ungültigkeit dieser Erklärung.

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Gert-Hartwig Lescow
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Anton Schrofner

CE 0123	**Appendix I to EC Declaration of Conformity** *Anlage I zur EU Konformitätserklärung*	Date / *Datum* 2020-06-04
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD101-035-2006-021-0-00

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Atlan	Anesthesia Workstation

Applied Standards in full or in part / *Vollständig oder teilweise angewendete Normen*:

EN 60601-1: 2006 + A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance
EN 60601-1-2: 2015 *(IEC 60601-1-2:2014)*	Medical Electrical Equipment - Part 1-2: General Requirements for basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
EN 60601-1-6: 2010 + AMD1:2015 *(IEC 60601-1-6: 2010 + A1:2013)*	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006 + AMD1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-13: 2011 + A1: 2015	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
EN ISO 80601-2-55: 2011 + COR:2012 *(ISO 80601-2-55: 2011)*	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 62304:2006 Amd 1:2015 *(IEC 62304 2006 Amd1:2015)*	Medical device software -Software life cycle processes
ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
EN ISO 14971: 2012 *(ISO 14971: 2007 COR)*	Medical devices - Application of risk management to medical devices
EN ISO 10993-1: 2009 + AC:2010 *(ISO 10993-1: 2009 + COR:2010)*	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*
Atlan	Anesthesia Workstation
Applied Standards in full or in part / *Vollständig oder teilweise angewendete Normen*:	
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN 1041: 2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2016 *(ISO 15223-1: 2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

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CE 0123	***Appendix II to EC Declaration of Conformity*** *Anlage II zur EU Konformitätserklärung*	Date / *Datum* 2020-06-04
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD101-035-2006-021-0-ECA

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Extent of conformity assessment / Umfang der Konformitätsbewertung	
Part No. / *Sach Nr.*	Product name / *Produktbezeichnung*
8621300	Atlan A300
8621400	Atlan A300 XL
8621500	Atlan A350
8621600	Atlan A350 XL

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