CE 0123	**EC Declaration of Conformity** *EG Konformitätserklärung*	Date / *Datum* 2015-01-15
	European Directive 93/42/EEC, Annex II *Europäische Richtlinie 93/42/EWG, Anhang II*	Document ID / *Dokument Nr.* MD108-006-1501-097-0

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

hereby declares that the / *erklärt hiermit, dass*

Product Name / *Produktbezeichnung*	Medical Device / *Medizinprodukt*	Device Class	UMDNS Code / GMDN Code
HME HumidStar	Heat and Moisture Exchanger	IIa	15-645 / 35530
HME HumidStar Trach	Heat and Moisture Exchanger	IIa	15-645 / 35530
Filter CareStar	Breathing Filter	IIa	14-352 / 35070
Filter SafeStar	Breathing Filter	IIa	14-352 / 35070
Filter/HME TwinStar	Breathing Filter; Heat and Moisture Exchanger	IIa	11-710 / 46816

meets the provisions of the European Directive 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.
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 Dräger will invalidate this declaration.

mit den Bestimmungen der europäischen Richtlinie 93/42/EWG (Medizinprodukte) übereinstimmt. 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.
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Dräger autorisierte Modifikation an dem Medizinprodukt führt zur Ungültigkeit dieser Erklärung.

Legal Counsel

Claus Martin Baumann

Director Regulatory & Clinical Affairs

Frank Clanzett

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Prof. Dr. Nikolaus Schweickart
Executive Board:
Stefan Dräger (chairman)
Dr. Herbert Fehrecke
Gert-Hartwig Lescow
Anton Schrofner

CE 0123	**Appendix II to EC Declaration of Conformity** *Anlage II zur EG Konformitätserklärung*	Date / *Datum* 2015-01-15
	European Directive 93/42/EEC *Europäische Richtlinie 93/42/EWG*	Document ID / *Dokument Nr.* MD108-006-1501-097-0-ECA

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Extent of conformity assessment / Umfang der Konformitätsbewertung				
Part No. / *Sach Nr.*	Product name / *Produktbezeichnung*		Part No. / *Sach Nr.*	Product name / *Produktbezeichnung*
MP01730	HME HumidStar 55		MP01790	Filter SafeStar 55
MP01735	HME HumidStar 25		MP01795	Filter SafeStar 60A
MP01740	HME HumidStar 10A		MP01800	Filter/HME TwinStar 90
MP01745	HME HumidStar 2		MP01801	Filter/HME TwinStar HEPA
MP01750	HME HumidStar Trach		MP01805	Filter/HME TwinStar 55
MP01755	Filter CareStar 45		MP01810	Filter/HME TwinStar 65A
MP01765	Filter CareStar 40A		MP01815	Filter/HME TwinStar 25
MP01770	Filter CareStar 30		MP01820	Filter/HME TwinStar 8
MP01785	Filter SafeStar 80		MP01825	Filter/HME TwinStar 10A

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CE 0123	**Appendix I to EC Declaration of Conformity** *Anlage zur I zur EG Konformitätserklärung*	Date / *Datum* 2015-01-15
	European Directive 93/42/EEC *Europäische Richtlinie 93/42/EWG*	Document ID / *Dokument Nr.* MD108-006-1501-097-0-00

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Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*
HME HumidStar	Heat and Moisture Exchanger
HME HumidStar Trach	Heat and Moisture Exchanger
Filter CareStar	Breathing Filter
Filter SafeStar	Breathing Filter
Filter/HME TwinStar	Breathing Filter; Heat and Moisture Exchanger

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

EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 23328-1:2008	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN 20594-1:1993/A1:1997	Conical Fittings with a 6 % (Luer) Taper for Syringes, Needles and certain other Medical Equipment - Part 1: General Requirements
EN 1707:1996	Conical Fittings with a 6 % (Luer) Taper for Syringes, Needles and certain other Medical Equipment - Lock Fittings
EN ISO 5356-1:2004	Anaesthetic and respiratory equipment – conical connectors – part 1: Cones and sockets
EN ISO 9360-1:2009	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISO 14971:2007	Medical Devices - Application of Risk Management to Medical Devices
EN 980:2008	Symbols for use in the labelling of medical devices

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