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Dräger

CE 0123	**EC Declaration of Conformity** *EG Konformitätserklärung*	Date / *Datum* 2020-09-09
	European Directive 93/42/EEC, Annex II **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG, Anhang II* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD101-031-2009-028-0

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

EC Certificate: G10105780037 Rev.01
Valid until: 2024-05-26

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
Perseus A500	Anesthesia System	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.

President Business Unit Therapy
Medical Division

Stephan Kruse

Drägerwerk AG & Co. KGaA Dräger Regulatory Affairs D-23542 Lübeck

Head of Quality & Business Excellence
Buisiness Unit Therapy

Dieter Kurzbach

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Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

REPUBLICA MOLDOVA SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNIPAMED-PLUS" IDNO 1003600077671

Dräger

CE 0123	**Appendix to EC Declaration of Conformity** *Anlage zur EG Konformitätserklärung*	Date / *Datum* 2020-09-09
	European Directive 93/42/EC **European Directive 2011/65/EC** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD101-031-2009-028-0-00

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*
Perseus A500	Anesthesia System
Applied Standards in full or in part / *Vollständig oder teilweise angewendete Normen*:	
EN 60601-1:2006 + AMD1:2013 + AMD12:2014 *(IEC 60601-1:2005 + AMD1 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 safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6: 2010 + AMD1:2015 *(IEC 60601-1-6:2010 + AMD1:2013)*	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366:2008 + AMD1:2015 *(IEC 62366:2007 + AMD1:2014)*	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 60601-1-8 :2007 / AC:2014 + AMD11:2017 *(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
EN ISO 80601-2-13:2012 *(ISO 80601-2-13:2011 + AMD1:2015)*	Medical electrical equipment -- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
EN ISO 10993-1:2009 / AC 2010 *(ISO 10993-1:2009 + COR1:2010)*	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 80601-2-55:2018 *(ISO 80601-2-55:2018)*	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 15001:2011 *(ISO 15001:2010)*	Anaesthetic and respiratory equipment -- Compatibility with oxygen
EN ISO 17664:2017 *(ISO 17664:2017)*	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

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Anton Schrofner

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CE 0123	***Appendix II to EC Declaration of Conformity*** *Anlage II zur EG Konformitätserklärung*	Date / *Datum* 2020-09-09
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD101-031-2009-028-0-ECA

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Extent of conformity assessment / Umfang der Konformitätsbewertung	
Part No. / ***Sach Nr.***	**Product name /** ***Produktbezeichnung***
MK06000	**Perseus A500** *SW Version: 2.03*
Variants:	**Trolley Version /** **Ceiling-mounted Version**
	Electronically Controlled Gas Mixer (Standard and Advanced Cylinder Support) / Mechanically Controlled Gas Mixer
	Cylinder standing / Cylinder hanging
	Auto Exclusion Version 2 Vapors / Auto Exclusion Version 3 Vapors
	Vapor View Option
Software Options:	Software option Auto On Software option Pressure Support Software option APRV Software option Econometer Trend Software option Oxygen Prediction Software option Low-flow Wizard Software option Breathing Sound Emulator Software option Agent Estimate Software option Lung Recruitment Software option Data Analysis Software option Workplace Functionality
MK09786	CK AGSS threaded jacket
MK09053	CK vapor view option for 3 Drä
MK09104	Flexibility trolley
MK10073	CK CD for non-Draeger CSU
MK09728	CK Software Options Perseus

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Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*
Perseus A500	Anesthesia System
Applied Standards in full or in part / *Vollständig oder teilweise angewendete Normen*:	
EN ISO 14971:2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN 62304:2006 + AMD1:2015 *(IEC 62304:2006 + AMD1:2015)*	Medical device software - Software life-cycle processes
EN ISO 15223-1:2016 + COR:2017 *(ISO 15223-1:2016 COR)*	Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices

President Business Unit Therapy
Medical Division

Stephan Kruse

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AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.come	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			Perseus A						
DM000422524	SISTEM DE ANESTEZIE		PERSEUS A500		Germania	DRAGERWERK AG & CO. KGAA	ECHIPAMED-PLUS S.R.L.	Rg04-000012	18-01-2023

Содержит([Model], 'Perseus A')