EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR101-035-2302-001-0**
Date / Datum	**2023-02-09**
Place / Ort	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Single registration number (SRN)/
einmalige Registrierungsnummer: DE-MF-000005329

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

Product Name / Produktbezeichnung	Device Category / Produktkategorie	Device Class / Geräteklasse	UMDNS Code / GMDN Code / EMDN Code
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

European regulation (EU) 2017/745 on medical devices. An examination of the quality management System has been carried out following Annex IX (Chapters I and III and section 4) of the regulation by the Notified Body:/ Verordnung (EU) 2017/745 über Medizinprodukte. Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang IX (Kapitel I and III und Abschnitt 4) der Verordnung beschrieben, wurde durch die Benannte Stelle vorgenommen: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
The quality management system also complies to EN ISO 9001 and EN ISO 13485./ Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment/ Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten

Dräger

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Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance /

Richtlinie 2014/53/EU des Europäischen Parlaments und des Rates vom 16. April 2014 über die Harmonisierung der Rechtsvorschriften der Mitgliedstaaten über die Bereitstellung von Funkanlagen auf dem Markt und zur Aufhebung der Richtlinie 1999/5/EG

This declaration is effective for products placed on the market as of the date of issue. Any modifications of the device not authorized by Dräger will invalidate this declaration./
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Dräger autorisierte Modifikation an dem Produkt führt zur Ungültigkeit dieser Erklärung.

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

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

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Atlan	**Anesthesia Equipment**
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

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Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Atlan	**Anesthesia Equipment**
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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ЕС декларация за съответствие

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EC Certificate: G10 010578 0039 Rev. 08
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Еднократен регистрационен номер (SRN): DE-MF-000005329

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код GMDN / Код EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

отговаря на следните разпоредби:

ЕВРОПЕЙСКИ РЕГЛАМЕНТ (ЕС) 2017/745 относно медицински изделия. Извършено е проучване на системата за управление на качеството в съответствие с анекс IX (глави I и III и раздел 4) на регламента от нотифицирания орган: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Системата за управление на качеството също отговаря на EN ISO 9001 и EN ISO 13485.
ДИРЕКТИВА 2011/65/ЕС НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 8 юни 2011 година относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване
ДИРЕКТИВА 2014/53/ЕС НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 16 април 2014 година за хармонизирането на законодателствата на държавите членки във връзка с предоставянето на пазара на радиосъоръжения и за отмяна на Директива 1999/5/ЕО

За продукти, пуснати на пазара, тази декларация е в сила от датата на издаване. Всяка модификация на уреда, която не е разрешена от Dräger, обезсилва тази декларация.

Това е превод на оригиналния документ (en/de) и затова не е подписан.

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ЕС декларация за съответствие

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Head of Competence Center Anesthesia
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Christian Engeln

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Име на продукта	**Категория на уреда**
Atlan	**Anesthesia Equipment**
Напълно или частично приложени стандарти:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
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EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Име на продукта	**Категория на уреда**
Atlan	**Anesthesia Equipment**
Напълно или частично приложени стандарти:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Обхват на оценката на съответствие		
Номер на частта	Име на продукта	Основен идентификатор UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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Declaración UE de conformidad

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EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Número de registro único (SRN): DE-MF-000005329

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

cumple las siguientes disposiciones:

REGLAMENTO EUROPEO (UE) 2017/745 sobre los productos sanitarios. Se ha efectuado un examen del sistema de gestión de la calidad siguiendo el anexo IX (capítulos I y III y sección 4) del reglamento del organismo notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
El sistema de gestión de la calidad también cumple con EN ISO 9001 y EN ISO 13485.
DIRECTIVA 2011/65/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos
DIRECTIVA 2014/53/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 16 de abril de 2014 relativa a la armonización de las legislaciones de los Estados miembros sobre la comercialización de equipos radioeléctricos, y por la que se deroga la Directiva 1999/5/CE

Esta declaración será efectiva para los productos puestos en el mercado a partir de la fecha de publicación. Cualquier modificación del dispositivo no autorizada por Dräger invalidará esta declaración.

Esta es una traducción del documento original (en/de) y, por lo tanto, no lleva firma.

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Nombre del producto	**Categoría del dispositivo**
Atlan	**Anesthesia Equipment**
Normas aplicadas total o parcialmente:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
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Nombre del producto	**Categoría del dispositivo**
Atlan	**Anesthesia Equipment**
Normas aplicadas total o parcialmente:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
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EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
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Dr. Reiner Piske
Anton Schrofner

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Declaración UE de conformidad

N.º de documento	**MDR101-035-2302-001-0**
Fecha	**2023-02-09**
Lugar	**Germany - Lübeck**
Página	**5 / 5**

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

Alcance de la evaluación de conformidad		
Número de referencia	Nombre del producto	UDI-DI básico
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Místo	**Germany - Lübeck**
Strana	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Jednorázové registračních číslo (SRN): DE-MF-000005329

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód GMDN / Kód EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 o zdravotnických prostředcích. Kontrola systému managementu kvality byla provedena oznámeným subjektem podle přílohy IX (kapitol I a III a oddílu 4) nařízení: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém managementu kvality splňuje rovněž požadavky norem EN ISO 9001 a EN ISO 13485.
SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních
SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2014/53/EU ze dne 16. dubna 2014 o harmonizaci právních předpisů členských států týkajících se dodávání rádiových zařízení na trh a zrušení směrnice 1999/5/ES

Toto prohlášení nabývá platnosti pro produkty uvedené na trh ke dni vydání. Jakákoli úprava prostředku, která není schválena společností Dräger, toto prohlášení zneplatní.

Toto je překlad původního dokumentu (en/de), a proto nenese podpis.

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VAT no. DE135082211

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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
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EU prohlášení o shodě

Č. dokumentu	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Místo	**Germany - Lübeck**
Strana	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

Drägerwerk AG & Co. KGaA
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EU prohlášení o shodě

Č. dokumentu	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Místo	**Germany - Lübeck**
Strana	**3 / 5**

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

Název produktu	**Kategorie prostředku**
Atlan	**Anesthesia Equipment**
Použité normy, v celku nebo z části:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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EU prohlášení o shodě

Č. dokumentu	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Místo	**Germany - Lübeck**
Strana	**4 / 5**

Název produktu	**Kategorie prostředku**
Atlan	**Anesthesia Equipment**
Použité normy, v celku nebo z části:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

Drägerwerk AG & Co. KGaA
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EU prohlášení o shodě

Č. dokumentu	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Místo	**Germany - Lübeck**
Strana	**5 / 5**

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

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

da

EU-overensstemmelseserklæring

CE 0123

Dokumentnr.	**MDR101-035-2302-001-0**
Dato	**2023-02-09**
Sted	**Germany - Lübeck**
Side	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Individuelt registreringsnummer (SRN): DE-MF-000005329

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

opfylder følgende bestemmelser:

EUROPÆISK FORORDNING (EU) 2017/745 om medicinsk udstyr. En undersøgelse af kvalitetsstyringssystemet er blevet foretaget i overensstemmelse med bilag IX (kapitel I og III og afsnit 4) til forordningen af det bemyndigede organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetsstyringssystemet overholder ligeledes EN ISO 9001 og EN ISO 13485.
EUROPA-PARLAMENTETS OG RÅDETS DIREKTIV 2011/65/EU af 8. juni 2011 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr
EUROPA-PARLAMENTETS OG RÅDETS DIREKTIV 2014/53/EU af 16. april 2014 om harmonisering af medlemsstaternes love om tilgængeliggørelse af radioudstyr på markedet og om ophævelse af direktiv 1999/5/EF

Denne erklæring gælder for produkter, der markedsføres efter udstedelsesdatoen. Ved enhver ændring af udstyret, der ikke er godkendt af Dräger, mister denne erklæring sin gyldighed.

Dette er en oversættelse af det originale dokument (en/de) og er derfor ikke forsynet med en underskrift.

Drägerwerk AG & Co. KGaA
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IBAN: DE15 2305 0101 0001 0711 17
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Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
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EU-overensstemmelseserklæring

Dokumentnr.	**MDR101-035-2302-001-0**
Dato	**2023-02-09**
Sted	**Germany - Lübeck**
Side	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR101-035-2302-001-0**
Dato	**2023-02-09**
Sted	**Germany - Lübeck**
Side	**3 / 5**

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

Produktnavn	**Apparatkategori**
Atlan	**Anesthesia Equipment**
Standarder, der anvendes helt eller delvist:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
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EN 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
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EU-overensstemmelseserklæring

Dokumentnr.	**MDR101-035-2302-001-0**
Dato	**2023-02-09**
Sted	**Germany - Lübeck**
Side	**4 / 5**

Produktnavn	**Apparatkategori**
Atlan	**Anesthesia Equipment**
Standarder, der anvendes helt eller delvist:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
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Side	**5 / 5**

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR101-035-2302-001-0**
Kuupäev	**2023-02-09**
Koht	**Germany - Lübeck**
Lk	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Kordumatu registreerimisnumber (SRN): DE-MF-000005329

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

vastab järgmistele nõuetele:

EUROOPA MÄÄRUS (EL) 2017/745 meditsiiniseadmete kohta. Kvaliteedijuhtimise süsteemi on hinnatud teavitatud asutuses määruse IX lisa (peatükid I ja III ning jaotis 4) alusel: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvaliteedikontrolli süsteem vastab ka standarditele EN ISO 9001 ja EN ISO 13485.
EUROOPA PARLAMENDI JA NÕUKOGU DIREKTIIV 2011/65/EL, 8. juuni 2011, teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes
EUROOPA PARLAMENDI JA NÕUKOGU DIREKTIIV 2014/53/EL, 16. aprill 2014, raadioseadmete turul kättesaadavaks tegemist käsitlevate liikmesriikide õigusaktide ühtlustamise kohta ja millega tunnistatakse kehtetuks direktiiv 1999/5/EÜ

Käesolev deklaratsioon kehtib toodete kohta, mis on turule toodud alates deklaratsiooni väljaandmise kuupäevast. Deklaratsioon kaotab kehtivuse, kui tootel tehakse muudatusi, mille kohta ei ole Drägerilt nõusolekut saadud.

Tegu on originaaldokumendi (en/de) tõlkega ja seetõttu ei ole sellel allkirja.

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR101-035-2302-001-0**
Kuupäev	**2023-02-09**
Koht	**Germany - Lübeck**
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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR101-035-2302-001-0**
Kuupäev	**2023-02-09**
Koht	**Germany - Lübeck**
Lk	**3 / 5**

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

Toote nimi	**Seadme kategooria**
Atlan	**Anesthesia Equipment**
Osaliselt või täielikult kohaldatud standardid:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
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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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR101-035-2302-001-0**
Kuupäev	**2023-02-09**
Koht	**Germany - Lübeck**
Lk	**4 / 5**

Toote nimi	**Seadme kategooria**
Atlan	**Anesthesia Equipment**
Osaliselt või täielikult kohaldatud standardid:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
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General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR101-035-2302-001-0**
Kuupäev	**2023-02-09**
Koht	**Germany - Lübeck**
Lk	**5 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR101-035-2302-001-0**
Ημερομηνία	**2023-02-09**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**1 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Μεμονωμένος αριθμός εγγραφής (SRN): DE-MF-000005329

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

συμμορφώνεται με τις ακόλουθες διατάξεις:

Ευρωπαϊκός κανονισμός (ΕΕ) 2017/745 περί ιατροτεχνολογικών προϊόντων. Πραγματοποιήθηκε έλεγχος του συστήματος διαχείρισης ποιότητας σύμφωνα με το παράρτημα IX (κεφάλαια I και III και ενότητα 4) του κανονισμού από τον κοινοποιημένο οργανισμό: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Το σύστημα διαχείρισης ποιότητας συμμορφώνεται επίσης με τα πρότυπα EN ISO 9001 και EN ISO 13485.
ΟΔΗΓΙΑ 2011/65/ΕΕ ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 8ης Ιουνίου 2011 για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό
ΟΔΗΓΙΑ 2014/53/ΕΕ ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 16ης Απριλίου 2014 σχετικά με την εναρμόνιση των νομοθεσιών των κρατών μελών σχετικά με τη διαθεσιμότητα ραδιοεξοπλισμού στην αγορά και την κατάργηση της οδηγίας 1999/5/ΕΚ

Η παρούσα δήλωση ισχύει για προϊόντα που τίθενται στην αγορά από την ημερομηνία έκδοσης. Οποιαδήποτε τροποποίηση στη συσκευή χωρίς την έγκριση της Dräger θα ακυρώσει την παρούσα δήλωση.

Το παρόν αποτελεί μετάφραση του πρωτότυπου εγγράφου (από τα αγγλικά/γερμανικά) και γι' αυτό το λόγο δεν φέρει σφραγίδα.

Δήλωση συμμόρφωσης ΕΕ

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Αρ. εγγράφου	**MDR101-035-2302-001-0**
Ημερομηνία	**2023-02-09**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Δήλωση συμμόρφωσης ΕΕ

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Ημερομηνία **2023-02-09**
Τοποθεσία **Germany - Lübeck**
Σελίδα **3 / 5**

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

Όνομα προϊόντος	**Κατηγορία συσκευής**
Atlan	**Anesthesia Equipment**
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR101-035-2302-001-0**
Ημερομηνία **2023-02-09**
Τοποθεσία **Germany - Lübeck**

Όνομα προϊόντος	**Κατηγορία συσκευής**
Atlan	**Anesthesia Equipment**
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
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Anton Schrofner

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR101-035-2302-001-0**
Ημερομηνία **2023-02-09**
Τοποθεσία **Germany - Lübeck**
Σελίδα **5 / 5**

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

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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Déclaration de conformité UE

N° du document	**MDR101-035-2302-001-0**
Date	**2023-02-09**
Ville	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
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Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Numéro d'enregistrement unique (SRN): DE-MF-000005329

déclare par la présente et sous sa seule responsabilité que le

Nom du produit	Catégorie de l'appareil	Classe de l'appareil	Code UMDNS / Code GMDN / Code EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

satisfait aux dispositions suivantes :

RÉGLEMENTATION EUROPÉENNE (UE) 2017/745 sur les dispositifs médicaux. Une vérification du système de gestion de la qualité a été réalisée conformément à l'annexe IX (chapitres I et III, ainsi que section 4) de la réglementation suivante par l'organisme notifié : **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Le système de gestion de la qualité satisfait également aux normes EN ISO 9001 et EN ISO 13485.
DIRECTIVE 2011/65/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques
DIRECTIVE 2014/53/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 16 avril 2014 relative à l'harmonisation des législations des États membres concernant la mise à disposition sur le marché d'équipements radioélectriques et abrogeant la directive 1999/5/CE

La déclaration s'applique aux produits mis sur le marché à partir de la date de publication. Toute modification non autorisée par Dräger apportée sur l'appareil rend cette déclaration caduque.

Il s'agit d'une traduction du document original (en/de) et ne porte donc pas de signature.

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Déclaration de conformité UE

N° du document	**MDR101-035-2302-001-0**
Date	**2023-02-09**
Ville	**Germany - Lübeck**
Page	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
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Dieter Kurzbach

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Executive Board:
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Déclaration de conformité UE

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Ville	**Germany - Lübeck**
Page	**3 / 5**

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

Nom du produit	**Catégorie de l'appareil**
Atlan	**Anesthesia Equipment**
Normes appliquées en totalité ou en partie :	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
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EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Déclaration de conformité UE

N° du document	**MDR101-035-2302-001-0**
Date	**2023-02-09**
Ville	**Germany - Lübeck**
Page	**4 / 5**

Nom du produit	**Catégorie de l'appareil**
Atlan	**Anesthesia Equipment**
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EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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Déclaration de conformité UE

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Ville	**Germany - Lübeck**
Page	**5 / 5**

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

Étendue de l'évaluation de la conformité		
Référence de pièce	Nom du produit	IUD-ID de base
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
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EU izjava o sukladnosti

Br. dokumenta	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Mjesto	**Germany - Lübeck**
Stranica	**1 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Jedinstveni registracijski broj (SRN): DE-MF-000005329

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 o medicinskim proizvodima. Ocjena sustava upravljanja kvalitetom provedena je prema Prilogu IX. (poglavlju I. i III. i stavku 4.) uredbe od strane prijavljenog tijela: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sustav upravljanja kvalitetom također je sukladan normama EN ISO 9001 i EN ISO 13485.
DIREKTIVA 2011/65/EU EUROPSKOG PARLAMENTA I VIJEĆA od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi
DIREKTIVA 2014/53/EU EUROPSKOG PARLAMENTA I VIJEĆA od 16. travnja 2014. o usklađivanju zakonodavstava država članica o stavljanju na raspolaganje radijske opreme na tržištu i stavljanju izvan snage Direktive 1999/5/EZ

Ova izjava za proizvode stavljene na tržište stupa na snagu od datuma izdavanja. U slučaju bilo kakvih izmjena proizvoda koje nisu odobrene od strane tvrtke Dräger ova izjava gubi svoju valjanost.

Ovo je prijevod izvornog dokumenta (engl./njem.) i stoga ne sadrži potpis.

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EU izjava o sukladnosti

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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk
Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board for
Drägerwerk AG & Co. KGaA and
Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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EU izjava o sukladnosti

Br. dokumenta	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Mjesto	**Germany - Lübeck**
Stranica	**3 / 5**

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

Naziv proizvoda	**Kategorija proizvoda**
Atlan	**Anesthesia Equipment**
Norme primijenjene u cijelosti ili djelomično:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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EU izjava o sukladnosti

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Atlan	**Anesthesia Equipment**
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Br. dokumenta	**MDR101-035-2302-001-0**
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Stranica	**5 / 5**

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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Dichiarazione di conformità UE

N. documento	**MDR101-035-2302-001-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Numero di registrazione unico (SRN): DE-MF-000005329

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

è conforme alle seguenti disposizioni:

REGOLAMENTO EUROPEO (UE) 2017/745 relativo ai dispositivi medici. È stata effettuata una verifica del sistema di gestione della qualità ai sensi dell'allegato IX (capitoli I e III e sezione 4) del regolamento dell'organismo notificato: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Il sistema di gestione della qualità è altresì conforme alle norme EN ISO 9001 e EN ISO 13485.
DIRETTIVA 2011/65/UE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche
DIRETTIVA 2014/53/UE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 16 aprile 2014 concernente l'armonizzazione delle legislazioni degli Stati membri relative alla messa a disposizione sul mercato di apparecchiature radio e che abroga la direttiva 1999/5/CE

La presente dichiarazione è valevole per i prodotti lanciati sul mercato a partire dalla data di pubblicazione. Qualsiasi modifica del dispositivo non autorizzata da Dräger invalida la presente dichiarazione.

Si tratta di una traduzione del documento originale (en/de) e non porta pertanto una firma.

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Dichiarazione di conformità UE

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Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Dichiarazione di conformità UE

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

Nome prodotto	**Categoria dispositivo**
Atlan	**Anesthesia Equipment**
Standard applicati integralmente o parzialmente:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
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Dichiarazione di conformità UE

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Luogo	**Germany - Lübeck**
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Nome prodotto	**Categoria dispositivo**
Atlan	**Anesthesia Equipment**
Standard applicati integralmente o parzialmente:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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Dichiarazione di conformità UE

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N. documento	**MDR101-035-2302-001-0**
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Luogo	**Germany - Lübeck**
Pagina	**5 / 5**

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

Estensione della valutazione di conformità		
Numero d'ordine	Nome prodotto	UDI-DI di base
8621300	**Atlan A300**	**04048675130103 5FK19Z000W9**
8621400	**Atlan A300 XL**	**04048675130103 5FK19Z000W9**
8621500	**Atlan A350**	**04048675130103 5FK19T010V2**
8621600	**Atlan A350 XL**	**04048675130103 5FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**04048675130103 5FK19X020VZ**

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR101-035-2302-001-0**
Datums	**2023-02-09**
Vieta	**Germany - Lübeck**
Lappuse	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Vienotais reģistrācijas numurs (VRN): DE-MF-000005329

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

atbilst šādiem noteikumiem:

EIROPAS REGULA (ES) 2017/745 par medicīnas ierīcēm. Kvalitātes vadības sistēmas pārbaudi veikusi pilnvarotā iestāde saskaņā ar regulas IX. pielikumu (nodaļas I un III, 4. sadaļa): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitātes vadības sistēma atbilst arī EN ISO 9001 un EN ISO 13485.
EIROPAS PARLAMENTA UN PADOMES DIREKTĪVA 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās
EIROPAS PARLAMENTA UN PADOMES DIREKTĪVA 2014/53/ES (2014. gada 16. aprīlis) par dalībvalstu tiesību aktu saskaņošanu attiecībā uz radioiekārtu pieejamību tirgū un ar ko atceļ Direktīvu 1999/5/EK

Šī deklarācija ir spēkā izstrādājumiem, kas laisti tirgū no izdošanas datuma. Jebkādi ierīces pārveidojumi, kurus nav atļāvis Dräger, padarīs šo deklarāciju par spēkā neesošu.

Šis ir oriģinālā dokumenta (en/de) tulkojums, tādēļ uz tā nav paraksta.

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Drägerwerk AG & Co. KGaA
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Izstrādājuma nosaukums	**Ierīces kategorija**
Atlan	**Anesthesia Equipment**
Pilnībā vai daļēji piemērotie standarti:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
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Izstrādājuma nosaukums	**Ierīces kategorija**
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Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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ES atitikties deklaracija

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EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Bendrasis registracijos numeris (BRN): DE-MF-000005329

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTA (ES) 2017/745 dėl medicinos prietaisų. Notifikuotoji įstaiga, atlikusi kokybės valdymo sistemos patikrinimą pagal reglamento IX priedą (I ir III skyrius bei 4 skirsnį): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kokybės valdymo sistema taip pat atitinka EN ISO 9001 ir EN ISO 13485 standartus.
EUROPOS PARLAMENTO IR TARYBOS DIREKTYVA 2011/65/ES 2011 m. birželio 8 d. dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo
EUROPOS PARLAMENTO IR TARYBOS DIREKTYVA 2014/53/ES 2014 m. balandžio 16 d. dėl valstybių narių įstatymų, susijusių su radijo įrenginių tiekimu rinkai, suderinimo, kuria panaikinama Direktyva 1999/5/EB

Ši deklaracija taikoma prietaisams, pateiktiems į rinką jų išleidimo dieną. Atlikus neleistinus „Dräger“ prietaiso keitimus, ši deklaracija taps negaliojanti.

Tai yra originalaus dokumento vertimas (iš anglų / vokiečių k.), todėl nereikia parašo.

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ES atitikties deklaracija

Dokumento Nr.	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Vieta	**Germany - Lübeck**
Psl.	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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VAT no. DE135082211

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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk
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Registered office: Lübeck
Commercial register:
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Psl.	**3 / 5**

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

Prietaiso pavadinimas	**Prietaiso kategorija**
Atlan	**Anesthesia Equipment**
Iš dalies ar visa apimtimi taikyti standartai:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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ES atitikties deklaracija

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Vieta	**Germany - Lübeck**
Psl.	**4 / 5**

Prietaiso pavadinimas	**Prietaiso kategorija**
Atlan	**Anesthesia Equipment**
Iš dalies ar visa apimtimi taikyti standartai:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Psl.	**5 / 5**

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR101-035-2302-001-0**
Dátum	**2023-02-09**
Hely	**Germany - Lübeck**
Oldal	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Egyedi regisztrációs szám (SRN): DE-MF-000005329

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

megfelel a következő rendelkezéseknek:

AZ EURÓPAI PARLAMENT ÉS A TANÁCS (EU) 2017/745 RENDELETE az orvostechnikai eszközökről. A minőségirányítási rendszer vizsgálatát a bejelentett szervezet az irányelv IX. melléklete (az I. és III. fejezet és a 4. szakasz) szerint végezte: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
A minőségirányítási rendszer megfelel továbbá az EN ISO 9001 és az EN ISO 13485 szabványoknak is.
AZ EURÓPAI PARLAMENT ÉS A TANÁCS 2011/65/EU IRÁNYELVE (2011. június 8.) egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról
AZ EURÓPAI PARLAMENT ÉS A TANÁCS 2014/53/EU IRÁNYELVE (2014. április 16.) a rádióberendezések forgalmazására vonatkozó tagállami jogszabályok harmonizációjáról és az 1999/5/EK irányelv hatályon kívül helyezéséről

Ez a nyilatkozat a kiállítását követően forgalomba hozott termékekre érvényes. A készüléken végzett bármilyen, a Dräger által nem engedélyezett módosítás érvényteleníti a nyilatkozatot.

Ez az eredeti dokumentum (en/de) fordítása, és ezért nem szerepel rajta aláírás.

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EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR101-035-2302-001-0**
Dátum	**2023-02-09**
Hely	**Germany - Lübeck**
Oldal	**2 / 5**

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EU megfelelőségi nyilatkozat

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Oldal	**3 / 5**

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

Termék neve	**Készülékkategória**
Atlan	**Anesthesia Equipment**
Teljesen vagy részben alkalmazott szabványok:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
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ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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EU megfelelőségi nyilatkozat

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Dátum	**2023-02-09**
Hely	**Germany - Lübeck**
Oldal	**4 / 5**

Termék neve	**Készülékkategória**
Atlan	**Anesthesia Equipment**
Teljesen vagy részben alkalmazott szabványok:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
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Dokumentum száma	**MDR101-035-2302-001-0**
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Hely	**Germany - Lübeck**
Oldal	**5 / 5**

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

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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EU-verklaring van overeenstemming

Documentnr.	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Plaats	**Germany - Lübeck**
Pagina	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Enkelvoudig registratienummer (SRN): DE-MF-000005329

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

voldoet aan de volgende bepalingen:

EUROPESE VERORDENING (EU) 2017/745 voor medische hulpmiddelen. De aangemelde instantie heeft het kwaliteitsborgingssysteem onderzocht overeenkomstig Bijlage IX (hoofdstukken I en III en deel 4) van de verordening: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Het kwaliteitsmanagementsysteem voldoet ook aan EN ISO 9001 en EN ISO 13485.
RICHTLIJN 2011/65/EU VAN HET EUROPEES PARLEMENT EN DE RAAD van 8 juni 2011 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.
RICHTLIJN 2014/53/EU VAN HET EUROPEES PARLEMENT EN DE RAAD van 16 april 2014 betreffende de harmonisatie van de wetgevingen van de lidstaten inzake het op de markt aanbieden van radioapparatuur en tot intrekking van Richtlijn 1999/5/EG

Deze verklaring geldt voor producten die op de markt zijn gebracht vanaf de datum van afgifte. Elke modificatie van het product waarvoor Dräger geen toestemming heeft gegeven, maakt deze verklaring ongeldig.

Dit is een vertaling van het originele document en benodigt derhalve geen ondertekening.

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EU-verklaring van overeenstemming

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Pagina	**2 / 5**

Head of Competence Center Anesthesia
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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Productnaam	**Apparaatcategorie**
Atlan	**Anesthesia Equipment**
Volledig of gedeeltelijk toegepaste normen:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
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ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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EU-verklaring van overeenstemming

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Plaats	**Germany - Lübeck**
Pagina	**4 / 5**

Productnaam	**Apparaatcategorie**
Atlan	**Anesthesia Equipment**
Volledig of gedeeltelijk toegepaste normen:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Drägerwerk AG & Co. KGaA
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Germany

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
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Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
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Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Miejsce	**Germany - Lübeck**
Strona	**1 / 5**

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

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Pojedynczy numer rejestracyjny (SRN): DE-MF-000005329

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod GMDN / Kod EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (EU) 2017/745 w sprawie wyrobów medycznych. Zostało przeprowadzone badanie systemu zarządzania jakością zgodnie z Załącznikiem IX (rozdziały I i III, sekcja 4) Rozporządzenia przez jednostkę notyfikowaną: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
System zarządzania jakością spełnia też normy EN ISO 9001 i EN ISO 13485.
DYREKTYWA PARLAMENTU EUROPEJSKIEGO I RADY 2011/65/UE z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym
DYREKTYWA PARLAMENTU EUROPEJSKIEGO I RADY 2014/53/UE z dnia 16 kwietnia 2014 r. w sprawie harmonizacji ustawodawstw państw członkowskich dotyczących udostępniania na rynku urządzeń radiowych i uchylająca dyrektywę 1999/5/WE

Niniejsza deklaracja dotyczy produktów wprowadzonych na rynek wg daty wydania. Wszelkie modyfikacje urządzenia niezatwierdzone przez Dräger spowodują utratę ważności niniejszej deklaracji.

Jest to tłumaczenie oryginalnego dokumentu i dlatego nie jest opatrzone podpisem.

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Deklaracja zgodności UE

Nr dokumentu	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Miejsce	**Germany - Lübeck**
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Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
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Dieter Kurzbach

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Strona	**3 / 5**

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

Nazwa produktu	**Kategoria urządzenia**
Atlan	**Anesthesia Equipment**
Zastosowane normy (w całości lub w części):	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Deklaracja zgodności UE

Nr dokumentu	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Miejsce	**Germany - Lübeck**
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Nazwa produktu	**Kategoria urządzenia**
Atlan	**Anesthesia Equipment**
Zastosowane normy (w całości lub w części):	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Deklaracja zgodności UE

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Miejsce	**Germany - Lübeck**
Strona	**5 / 5**

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

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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Declaração de conformidade da UE

Nº. do documento	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Local	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

O número de registro único (SRN): DE-MF-000005329

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

está em conformidade com as seguintes disposições:

REGULAMENTO (UE) 2017/745 relativo aos dispositivos médicos. Um exame do sistema de gerenciamento de qualidade foi realizado seguindo o Anexo IX (Capítulos I e III e a seção 4) do regulamento pelo Órgão notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
O sistema de gerenciamento de qualidade também está em conformidade com a EN ISO 9001 e a EN ISO 13485.
DIRETIVA 2011/65/UE DO PARLAMENTO EUROPEU E DO CONSELHO de 8 de junho de 2011 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrônicos
DIRETIVA 2014/53/UE DO PARLAMENTO EUROPEU E DO CONSELHO de 16 de abril de 2014 relativa à harmonização da legislação dos Estados-Membros respeitante à disponibilização de equipamentos de rádio no mercado e que revoga a Diretiva 1999/5/CE

Esta declaração é válida para produtos colocados no mercado a partir da data de emissão. Quaisquer modificações no equipamento não autorizadas pela Dräger invalidarão esta declaração.

Este documento é uma tradução do documento original (en/de) e, portanto, não precisa ser assinado.

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Declaração de conformidade da UE

Nº. do documento	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Local	**Germany - Lübeck**
Página	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

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Dieter Kurzbach

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IBAN: DE15 2305 0101 0001 0711 17
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Declaração de conformidade da UE

Nº. do documento	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Local	**Germany - Lübeck**
Página	**3 / 5**

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

Nome do produto	**Categoria do equipamento**
Atlan	**Anesthesia Equipment**
Normas aplicadas total ou parcialmente:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
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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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Declaração de conformidade da UE

Nº. do documento	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Local	**Germany - Lübeck**
Página	**4 / 5**

Nome do produto	**Categoria do equipamento**
Atlan	**Anesthesia Equipment**
Normas aplicadas total ou parcialmente:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
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Local	**Germany - Lübeck**
Página	**5 / 5**

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

Extensão da avaliação de conformidade		
Número da peça	Nome do produto	UDI-DI básico
8621300	**Atlan A300**	**04048675130103 5FK19Z000W9**
8621400	**Atlan A300 XL**	**04048675130103 5FK19Z000W9**
8621500	**Atlan A350**	**04048675130103 5FK19T010V2**
8621600	**Atlan A350 XL**	**04048675130103 5FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**04048675130103 5FK19X020VZ**

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Declaraţie de conformitate UE

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Drägerwerk AG & Co. KGaA
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23542 Lübeck
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EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Număr unic de înregistrare (SRN): DE-MF-000005329

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.
DIRECTIVA 2011/65/UE A PARLAMENTULUI EUROPEAN ȘI A CONSILIULUI din 8 iunie 2011 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice
DIRECTIVA 2014/53/UE A PARLAMENTULUI EUROPEAN ȘI A CONSILIULUI din 16 aprilie 2014 privind armonizarea legislației statelor membre referitoare la punerea la dispoziție pe piață a echipamentelor radio și de abrogare a Directivei 1999/5/CE

Această declaraţie are efect pentru produsele puse pe piaţă începând cu data emiterii. Orice modificare a dispozitivului neautorizată de Dräger va anula această declaraţie.

Aceasta este o traducere a documentului original (en/de) şi din această cauză nu necesită o semnătură.

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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Numele produsului	**Categoria dispozitivului**
Atlan	**Anesthesia Equipment**
Standarde aplicate în totalitate sau parţial:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
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EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Declaraţie de conformitate UE

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Data	**2023-02-09**
Localitatea	**Germany - Lübeck**
Pagina	**4 / 5**

Numele produsului	**Categoria dispozitivului**
Atlan	**Anesthesia Equipment**
Standarde aplicate în totalitate sau parţial:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

Drägerwerk AG & Co. KGaA
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www.draeger.com
VAT no. DE135082211

Bank details:
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IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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Declaraţie de conformitate UE

Nr. document	**MDR101-035-2302-001-0**
Data	**2023-02-09**
Localitatea	**Germany - Lübeck**
Pagina	**5 / 5**

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

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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EÚ vyhlásenie o zhode

Dokument č.	**MDR101-035-2302-001-0**
Dátum	**2023-02-09**
Miesto	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Jedinečné registračné číslo (SRN): DE-MF-000005329

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód GMDN / Kód EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

spĺňa nasledujúce nariadenia:

EURÓPSKE NARIADENIE (EÚ) 2017/745 o zdravotníckych pomôckach. Preskúmanie systému riadenia kvality bolo vykonané notifikovaným orgánom podľa prílohy IX (kapitoly I a III a oddielu 4) nariadenia: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém riadenia kvality tiež spĺňa normy STN EN ISO 9001 a STN EN ISO 13485.
SMERNICA EURÓPSKEHO PARLAMENTU A RADY 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach
SMERNICA EURÓPSKEHO PARLAMENTU A RADY 2014/53/EÚ zo 16. apríla 2014 o harmonizácii právnych predpisov členských štátov týkajúcich sa sprístupňovania rádiových zariadení na trhu, ktorou sa zrušuje smernica 1999/5/ES

Toto vyhlásenie pre výrobky uvedené na trh nadobúda platnosť dňom vydania. Akékoľvek zmeny zariadenia, ktoré neschválila spoločnosť Dräger, vedú k strate platnosti tohto vyhlásenia.

Toto je preklad pôvodného dokumentu (en/de) a preto na ňom nie je uvedený podpis.

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EÚ vyhlásenie o zhode

Dokument č.	**MDR101-035-2302-001-0**
Dátum	**2023-02-09**
Miesto	**Germany - Lübeck**
Strana	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Dokument č.	**MDR101-035-2302-001-0**
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Miesto	**Germany - Lübeck**
Strana	**3 / 5**

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

Názov výrobku	**Kategória zariadenia**
Atlan	**Anesthesia Equipment**
Použité normy v úplnom alebo v čiastočnom znení:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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EÚ vyhlásenie o zhode

Dokument č.	**MDR101-035-2302-001-0**
Dátum	**2023-02-09**
Miesto	**Germany - Lübeck**
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Názov výrobku	**Kategória zariadenia**
Atlan	**Anesthesia Equipment**
Použité normy v úplnom alebo v čiastočnom znení:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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Dr. Reiner Piske
Anton Schrofner

EÚ vyhlásenie o zhode

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Strana	**5 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Rozsah posúdenia zhody		
Objednávacie číslo	Názov výrobku	Základné UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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Izjava EU o skladnosti

Št. dokumenta	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Kraj	**Germany - Lübeck**
Stran	**1 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Enotna registrska številka (SRN): DE-MF-000005329

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

izpolnjuje naslednje določbe:

EVROPSKA UREDBA (EU) 2017/745 o medicinskih pripomočkih. Sistem upravljanja kakovosti je na podlagi Priloge IX (poglavji I in III in razdelek 4) uredbe preveril priglašeni organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistem upravljanja kakovosti je skladen tudi z EN ISO 9001 in EN ISO 13485.
DIREKTIVA 2011/65/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi
DIREKTIVA 2014/53/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 16. aprila 2014 o harmonizaciji zakonodaj držav članic v zvezi z dostopnostjo radijske opreme na trgu in razveljavitvi Direktive 1999/5/ES

Ta izjava velja za izdelke, na trg dane z datumom izdaje. Vsaka sprememba naprave brez soglasja družbe Dräger razveljavi to izjavo.

To je prevod originalnega dokumenta (en/de) in zato ni podpisan.

CE 0123

Izjava EU o skladnosti

Št. dokumenta	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Kraj	**Germany - Lübeck**
Stran	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

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Izjava EU o skladnosti

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Kraj	**Germany - Lübeck**
Stran	**3 / 5**

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

Ime izdelka	**Kategorija naprave**
Atlan	**Anesthesia Equipment**
V celoti ali deloma uporabljeni standardi:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
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EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Izjava EU o skladnosti

Št. dokumenta	**MDR101-035-2302-001-0**
Datum	**2023-02-09**
Kraj	**Germany - Lübeck**
Stran	**4 / 5**

Ime izdelka	**Kategorija naprave**
Atlan	**Anesthesia Equipment**
V celoti ali deloma uporabljeni standardi:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Izjava EU o skladnosti

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Datum	**2023-02-09**
Kraj	**Germany - Lübeck**
Stran	**5 / 5**

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

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
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Anton Schrofner

CE 0123

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR101-035-2302-001-0**
Päivämäärä	**2023-02-09**
Paikka	**Germany - Lübeck**
Sivu	**1 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Rekisterinumero: DE-MF-000005329

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 lääkinnällisistä laitteista. Laatujärjestelmän on tarkastanut asetuksen liitettä IX (I ja III luvun 4 kohtaa) noudattaen seuraava ilmoitettu laitos: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Laatujärjestelmä täyttää lisäksi standardien EN ISO 9001 ja EN ISO 13485 vaatimukset.
EUROOPAN PARLAMENTIN JA NEUVOSTON DIREKTIIVI 2011/65/EU, annettu 8 päivänä kesäkuuta 2011, tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa
EUROOPAN PARLAMENTIN JA NEUVOSTON DIREKTIIVI 2014/53/EU, annettu 16 päivänä huhtikuuta 2014, radiolaitteiden asettamista saataville markkinoilla koskevan jäsenvaltioiden lainsäädännön yhdenmukaistamisesta ja direktiivin 1999/5/EY kumoamisesta

Tätä vakuutusta sovelletaan tuotteisiin, jotka on saatettu markkinoille antamispäivästä alkaen. Laitteeseen tehtävät muutokset, joita Dräger ei ole hyväksynyt, mitätöivät tämän vakuutuksen.

Tämä on alkuperäisen (saksan-/englanninkielisen) asiakirjan käännös, eikä siinä siksi ole allekirjoitusta.

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Commercial register:
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Anton Schrofner

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR101-035-2302-001-0**
Päivämäärä	**2023-02-09**
Paikka	**Germany - Lübeck**
Sivu	**2 / 5**

Head of Competence Center Anesthesia
Business Unit Therapy

Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Asiakirjan nro **MDR101-035-2302-001-0**
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Paikka **Germany - Lübeck**
Sivu **3 / 5**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Tuotenimi	**Laitteen luokitus**
Atlan	**Anesthesia Equipment**
Kokonaan tai osittain sovellettavat standardit:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
IEC 60601-1-8:2006, AMD1:2012+A2:2020	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 AMD1:2015+AMD2:2018	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Tuotenimi	**Laitteen luokitus**
Atlan	**Anesthesia Equipment**
Kokonaan tai osittain sovellettavat standardit:	
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	Medical devices - Application of usability engineering to medical Devices
EN ISO 15223-1:2021 (ISO 15223-1:2012-07)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019+A11:2021 (ISO 14971:2019)	Medical Devices – Application of Risk Management to Medical Devices

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Drägerwerk AG & Co. KGaA
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Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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EU-försäkran om överensstämmelse

Dokument nr.	**MDR101-035-2302-001-0**
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Drägerwerk AG & Co. KGaA
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23542 Lübeck
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EC Certificate: G10 010578 0039 Rev. 08
Valid until: 2025-03-17

Enkelt registreringsnummer (SRN): DE-MF-000005329

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
Atlan SW 02.00.nn	Anesthesia Equipment	IIb	UMDNS 10-134 / GMDN 37710/ EMDN Z120301

uppfyller följande bestämmelser:

EUROPEISKA FÖRORDNINGEN (EU) 2017/745 om medicintekniska produkter. En undersökning av kvalitetshanteringssystemet har utförts enligt bilaga IX (kapitel I och III och avsnitt 4) till förordningen av det anmälda organet: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetshanteringssystemet uppfyller även EN ISO 9001 och EN ISO 13485.
EUROPAPARLAMENTETS OCH RÅDETS DIREKTIV 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning
EUROPAPARLAMENTETS OCH RÅDETS DIREKTIV 2014/53/EU av den 16 april 2014 om harmonisering av medlemsstaternas lagstiftning om tillhandahållande på marknaden av radioutrustning och om upphävande av direktiv 1999/5/EG

Denna försäkran gäller för produkter som släpps ut på marknaden från och med utgivningsdatum. Alla ändringar av enheten som inte godkänts av Dräger ogiltiggör denna försäkran.

Detta är en översättning av originaldokument (en/de) och därför har det inte någon signatur.

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Head of Competence Center Anesthesia
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Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Produktnamn	**Enhetskategori**
Atlan	**Anesthesia Equipment**
Helt eller delvis tillämpade standarder:	
EN 60601-1:2006 + A1:2013 + A12:2014+A2:2021 (IEC 60601-1: 2005 + A1:2012+A2:2020)	Medical electrical equipment - Part 1: General requirements for safety;
EN 60601-1-2:2015 + A1:2021 (IEC 60601-1-2: 2014 + AMD1:2020)	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standards:Electromanetic Compatibility , Requirements and Test
EN 60601-1-6: 2010 AMD1:2015+A2:2021 (IEC 60601-1-62010 AMD1:2013, AMD2:2020)	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
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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 62304:2006 A1:2015 IEC 62304:2006 A1:2015	Medical device software -Software life cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
EN ISO 18562-1:2020 ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process

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Sida **4 / 5**

Produktnamn	**Enhetskategori**
Atlan	**Anesthesia Equipment**
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EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
8621300	**Atlan A300**	**040486751301035FK19Z000W9**
8621400	**Atlan A300 XL**	**040486751301035FK19Z000W9**
8621500	**Atlan A350**	**040486751301035FK19T010V2**
8621600	**Atlan A350 XL**	**040486751301035FK19T010V2**
8621770	**SW Upgrade kit SW 1.0n to SW 2.0n (CK Software 2.n Atlan)**	**040486751301035FK19X020VZ**

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