axcent medical

LYRA Ventilaters

LYRA X1 ,X2

LYRA x1

Best Performing and Versatile Neonatal to Adult Ventilation in Hospital Environments

A compact turbine driven ventilator with multi-function, covers the non-invasive and invasive ventilation, and is suitable for treatment of most patient type. LYRA x1 is versatile throughout hospital and transport. Comprehensive ventilating modes, including APRV, PRVC, NIV are available for all your demands and for all type of patients from neonatal (optional) to adult. A collapsible high-resolution touch-screen display makes LYRA x1 mounted on a trolley your choice for ICU applications, as well as a high performance ventilator throughout hospital and transport. The innovative expiration valve disassembling concept brings more ease and efficiency for the sterilization process. As your versatile assistant, LYRA x1 is configured with O2 therapy, P-V tool, a lung titrating gold standard, etc.

Certificate - Declaration Of Conformity

Konfomitätserklärung *EC-Declaration of Conformity*		axcent medical	
		Dok.-Nr.:	F 711-004
		Date:	09.10.2019
Projekt-Nr.:	PM-04-001	Revision:	1.2
Projekt:	Beatmungsgerät	Page	1 / 1

im Sinne der Richtlinie 93/42/EWG des Rates über Medizinprodukte
according to 93/42 EEC Medical Device Directive

Wir, das Unternehmen
We as responsible manufacturer

aXcent medical GmbH
Josef-Görres-Platz 2
56068 Koblenz / Germany

erklären hiermit in alleiniger Verantwortung die Konformität des Medizinproduktes / *declare that this product*

Gerätetyp / *type of device*:
Bezeichnung des Gerätes / *name of device*:
Artikel-Nummer / *article-number*:

Beatmungsgerät / *Ventilator*
LYRA x1
400-100

Zweckbestimmung /
Intended Use:

Gerät zur Aufrechterhaltung und Unterstützung der menschlichen Atemfunktion
Device to maintain and support human ventilation

mit allen anwendbaren Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG Anhang II ohne (4).

is developed, constructed and manufactured in conformity all applicable requirements of Medical Device Directive ***93/42 EEC****, annex II without (4).*

Benannte Stelle / *notified body*:
Adresse / *address*:
Kenn-Nummer / ID-*number*:
Reg.-Nr. / *registration no*:

TÜV SÜD PRODUCT SERVICE GMBH
Ridlerstrasse 65
80339 München / Germany
0123
G1 101 259 0002

Konformitätsbewertungsverfahren: nach Anhang II ohne (4) der Richtlinie 93/42/EWG
conformity-assessment method: acc. Annex II excluding (4) of guideline 93/42 EEC

Klassifizierungsverfahren: Klasse IIb nach Anhang IX Regel 11 der Richtlinie 93/42/EWG
classification method: acc. annex IX rule 11 of guideline 93/42 EEC; this product is codified to class IIb.

Koblenz, Oct 09th, 2019

Torsten Kullmann
General Manager

Sascha Tietz
Product Management

Certificate - FDA EUA Authorization

FDA EUA Authorization Email

Good day. The Lyra x1 and Lyra x2 Ventilators for which you have requested authorization are within the scope of the emergency use authorization (EUA) issued on March 24, 2020.

FDA has determined that the Lyra x1 and Lyra x2 Ventilators models meet the criteria for safety, performance and labeling set forth in Section II and Appendix A of the EUA. As such, the specific Lyra x1 and Lyra x2 Ventilators models in your email are authorized for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the EUA, and have been added to Appendix B of the EUA. The emergency use of the Lyra x1 and Lyra x2 Ventilators under this EUA must be consistent with the terms of the EUA, including the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and Criteria for Safety, Performance and Labeling (Appendix A).

Best,

CDRH Non-Diagnostic EUA Team

Lanick Med Systems LLC	Lyra x1 and Lyra x2 Ventilators	Ventilator, Continuous, Facility Use	The LYRA xl ventilator is a mechanical ventilator designed to provide invasive and noninvasive, continuous or intermittent. respiratory support for pediatric and adult patients. Intended areas of use: • In the intensive care ward or in the recovery room. • During transfer of-ventilated patients within the hospital. The LYRA xl ventilator is intended for use by qualified. trained personnel under the direction of a physician and within the limits of its stated technical specifications. The LYRA x2 ventilator is a mechanical ventilator designed to provide invasive and noninvasive, continuous or intermittent, respiratory support for pediatric and adult patients. Intended areas of use: • In the intensive care ward or in the recovely room • During transfer of ventilated patients within the hospital. The LYRA x2 ventilator is intended for use by qualified, trained personnel under the direction of a of a physician and within the limits of its stated technical specifications.	May 12, 2020

Certificate - FDA Labeling - for Healthcare

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of Ventilators During the COVID-19 Pandemic **March 24, 2020**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators" in this Fact Sheet), ventilator tubing connectors, and ventilator accessories.

Certain ventilators, ventilator tubing connectors, and ventilator accessories are authorized for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

All patients who are treated with authorized ventilators during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of ventilators?

- Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- Ventilators found in the list of authorized products are authorized for use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.
- For each device, healthcare providers should review the instructions for use, including device specifications, reprocessing instructions (if applicable), and other labeling information.
- During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter. Healthcare providers should review additional device specifications, labeling, and patient monitoring recommendations in these circumstances.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of ventilators?

Potential benefits of ventilators include:

- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:

- Device malfunctions or adverse events
- Potential infectious and mechanical complications from sharing one ventilator through the use of multiplexing adapters have not been studied, and therefore caution is advised
- Risks of modified ventilator devices have not been studied, and therefore caution is advised

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

- Risks associated with the potential reduced requirements for alarms and monitoring of patients
- Reduced familiarity of healthcare providers with novel technologies used to treat patients

What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?

Alternatives to traditional ventilators that are authorized under this Emergency Use Authorization (EUA) include anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:

- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

- A positive pressure breathing device cannot offer all of the support that a traditional mechanical ventilator can
- A positive pressure breathing device may expose others to aerosols that could be contagious
- Healthcare providers other than trained anesthesia providers may not be familiar with the operation of anesthesia equipment, and therefore should pay careful attention to the instructions for use to avoid use error

What is an EUA?

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

Certificate - ISO 13485 - 2016

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 101259 0001 Rev. 01

Holder of Certificate: **aXcent medical GmbH**
Josef-Görres-Platz 2
56068 Koblenz
GERMANY

Facility(ies): aXcent medical GmbH
Dr.-Walter-Lessing-Str. 4, 56112 Lahnstein, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production, distribution and service of patient monitors, anesthesia devices and ventilators**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713154534

Valid from: 2019-09-13
Valid until: 2021-12-09

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Certificate - MDD-9342-CE

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101259 0002 Rev. 01

Manufacturer: **aXcent medical GmbH**
Josef-Görres-Platz 2
56068 Koblenz
GERMANY

Facility(ies): aXcent medical GmbH
Dr.-Walter-Lessing-Str. 4, 56112 Lahnstein, GERMANY

Product Category(ies): **patient monitors, anesthesia devices, ventilators**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713154534

Valid from: 2019-09-13
Valid until: 2023-12-09

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

LYRA x2

Top notch Performance of Non-Invasive and Invasive Ventilation for all Patient Categories

LYRA x2 is a premium non-invasive turbine driven ventilator with no compromise on the performance in invasive ventilation. User can easily switch between NIV- and IV-modes by UI operation only. Comprehensive parameter monitoring describes the full scenario of patient's status to the care giver. In a busy ICU it is imperative to give the desired mechanical ventilation to the patient. An 18.5 inch vertical layout touchscreen display makes operating of the ventilator smooth & easy.

Certificate - Declaration Of Conformity

Konfomitätserklärung *EC-Declaration of Conformity*		aXcent medical	
		Dok.-Nr.:	F 711-004
		Date:	07.05.2019
Projekt-Nr.:	PM-04-001	Revision:	1.1
Projekt:	Beatmungsgerät	Page	1 / 1

im Sinne der Richtlinie 93/42/EWG des Rates über Medizinprodukte
according to 93/42 EEC Medical Device Directive

Wir, das Unternehmen
We as responsible manufacturer

aXcent medical GmbH
Josef-Görres-Platz 2
56068 Koblenz / Germany

erklären hiermit in alleiniger Verantwortung die Konformität des Medizinproduktes / *declare that this product*

Gerätetyp / *type of device*:
Bezeichnung des Gerätes / *name of device*:
Artikel-Nummer / *article-number*:

Beatmungsgerät / *Ventilator*
LYRA x2
400-200

Zweckbestimmung /
Intended Use:

Gerät zur Aufrechterhaltung und Unterstützung der menschlichen Atemfunktion
Device to maintain and support human ventilation

mit allen anwendbaren Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG Anhang II ohne (4).

*is developed, constructed and manufactured in conformity all applicable requirements of Medical Device Directive **93/42 EEC**, annex II without (4).*

Benannte Stelle / *notified body*:
Adresse / *address*:
Kenn-Nummer / ID-*number*:
Reg.-Nr. / *registration no*:

TÜV SÜD PRODUCT SERVICE GMBH
Ridlerstrasse 65
80339 München / Germany
0123
G1 101 259 0002

Konformitätsbewertungsverfahren: nach Anhang II ohne (4) der Richtlinie 93/42/EWG
conformity-assessment method: acc. Annex II excluding (4) of guideline 93/42 EEC

Klassifizierungsverfahren: Klasse IIb nach Anhang IX Regel 11 der Richtlinie 93/42/EWG
classification method: acc. annex IX rule 11 of guideline 93/42 EEC; this product is codified to class IIb.

Koblenz, Oct 09th, 2019

Torsten Kullmann
General Manager

Sascha Tietz
Product Management

Certificate - FDA EUA Authorization

FDA EUA Authorization Email

Good day. The Lyra x1 and Lyra x2 Ventilators for which you have requested authorization are within the scope of the emergency use authorization (EUA) issued on March 24, 2020.

FDA has determined that the Lyra x1 and Lyra x2 Ventilators models meet the criteria for safety, performance and labeling set forth in Section II and Appendix A of the EUA. As such, the specific Lyra x1 and Lyra x2 Ventilators models in your email are authorized for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the EUA, and have been added to Appendix B of the EUA. The emergency use of the Lyra x1 and Lyra x2 Ventilators under this EUA must be consistent with the terms of the EUA, including the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and Criteria for Safety, Performance and Labeling (Appendix A).

Best,

CDRH Non-Diagnostic EUA Team

Lanick Med Systems LLC	Lyra x1 and Lyra x2 Ventilators	Ventilator, Continuous, Facility Use	The LYRA xl ventilator is a mechanical ventilator designed to provide invasive and noninvasive, continuous or intermittent. respiratory support for pediatric and adult patients. Intended areas of use: • In the intensive care ward or in the recovery room. • During transfer of-ventilated patients within the hospital. The LYRA xl ventilator is intended for use by qualified. trained personnel under the direction of a physician and within the limits of its stated technical specifications. The LYRA x2 ventilator is a mechanical ventilator designed to provide invasive and noninvasive, continuous or intermittent, respiratory support for pediatric and adult patients. Intended areas of use: • In the intensive care ward or in the recovely room • During transfer of ventilated patients within the hospital. The LYRA x2 ventilator is intended for use by qualified, trained personnel under the direction of a of a physician and within the limits of its stated technical specifications.	May 12, 2020

Certificate - FDA Labeling - for Healthcare

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of Ventilators During the COVID-19 Pandemic **March 24, 2020**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators" in this Fact Sheet), ventilator tubing connectors, and ventilator accessories.

Certain ventilators, ventilator tubing connectors, and ventilator accessories are authorized for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

All patients who are treated with authorized ventilators during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of ventilators?

- Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- Ventilators found in the list of authorized products are authorized for use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.
- For each device, healthcare providers should review the instructions for use, including device specifications, reprocessing instructions (if applicable), and other labeling information.
- During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter. Healthcare providers should review additional device specifications, labeling, and patient monitoring recommendations in these circumstances.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of ventilators?

Potential benefits of ventilators include:

- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:

- Device malfunctions or adverse events
- Potential infectious and mechanical complications from sharing one ventilator through the use of multiplexing adapters have not been studied, and therefore caution is advised
- Risks of modified ventilator devices have not been studied, and therefore caution is advised

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

- Risks associated with the potential reduced requirements for alarms and monitoring of patients
- Reduced familiarity of healthcare providers with novel technologies used to treat patients

What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?

Alternatives to traditional ventilators that are authorized under this Emergency Use Authorization (EUA) include anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:

- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

- A positive pressure breathing device cannot offer all of the support that a traditional mechanical ventilator can
- A positive pressure breathing device may expose others to aerosols that could be contagious
- Healthcare providers other than trained anesthesia providers may not be familiar with the operation of anesthesia equipment, and therefore should pay careful attention to the instructions for use to avoid use error

What is an EUA?

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

Certificate - ISO 13485 - 2016

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 101259 0001 Rev. 01

Holder of Certificate: **aXcent medical GmbH**
Josef-Görres-Platz 2
56068 Koblenz
GERMANY

Facility(ies): aXcent medical GmbH
Dr.-Walter-Lessing-Str. 4, 56112 Lahnstein, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production, distribution and service of patient monitors, anesthesia devices and ventilators**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713154534

Valid from: 2019-09-13
Valid until: 2021-12-09

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

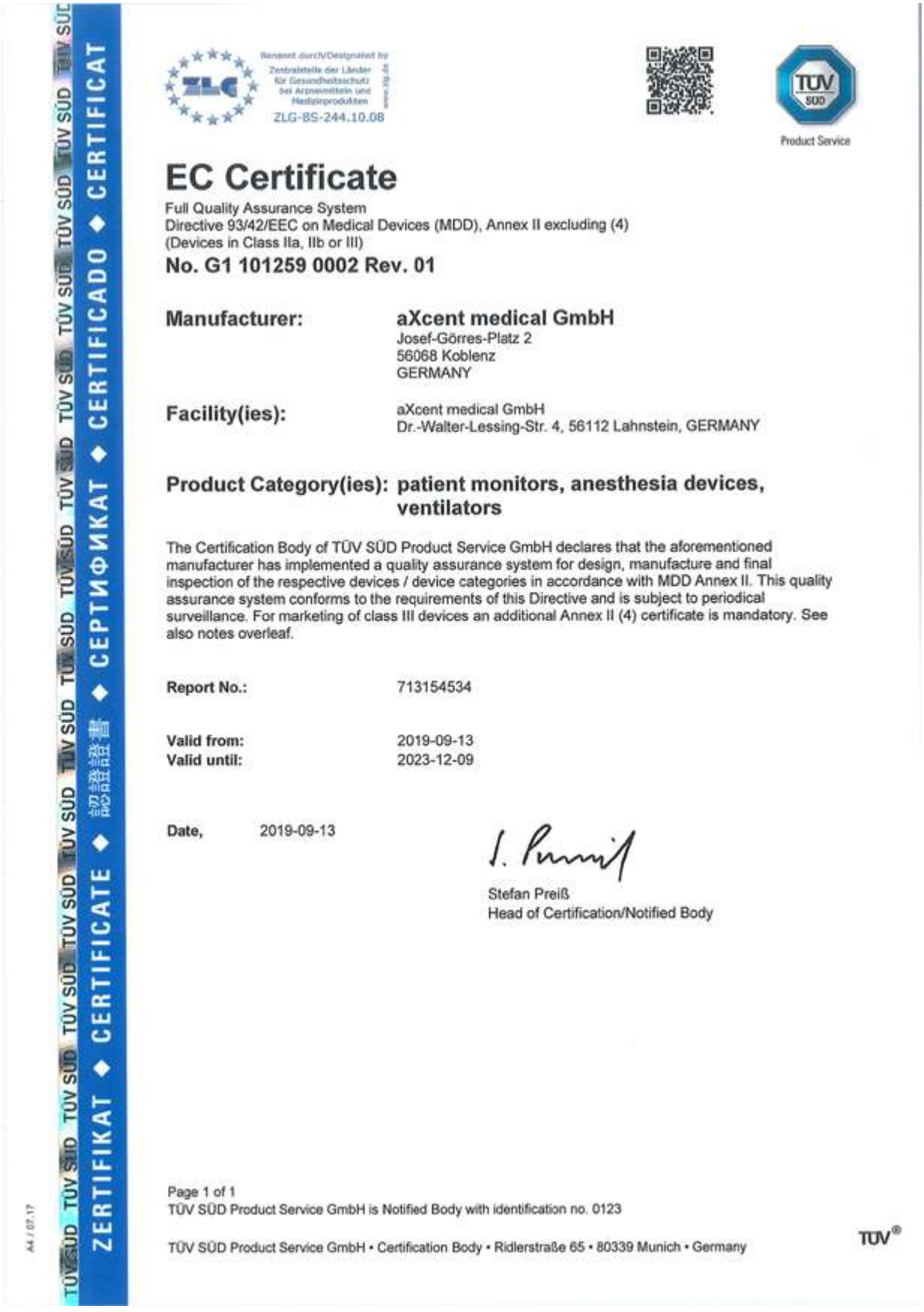
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

Certificate - MDD-9342-CE



Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101259 0002 Rev. 01

Manufacturer: **aXcent medical GmbH**
Josef-Görres-Platz 2
56068 Koblenz
GERMANY

Facility(ies): aXcent medical GmbH
Dr.-Walter-Lessing-Str. 4, 56112 Lahnstein, GERMANY

Product Category(ies): **patient monitors, anesthesia devices, ventilators**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713154534

Valid from: 2019-09-13
Valid until: 2023-12-09

Date, 2019-09-13

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Contact info

Mob: +44 - 7452 926055 **Mail:** saleskl@srammram.com

www.srammram.com