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. 02

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

Product Category(ies): **patient monitors, anesthesia devices, ventilators, transport 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.: 713172443

Valid from: 2020-03-03
Valid until: 2023-12-09

Date, 2020-03-03

Christoph Dicks
Head of Certification/Notified Body

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

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.09.14 14:57:42 EEST
Reason: MoldSign Signature
Location: Moldova

Konfomitätserklärung

EC-Declaration of Conformity

		Dok.-Nr.:	F 711-004
		Date:	09.10.2019
Projekt-Nr.:	PM-01-001	Revision:	1.2
Projekt:	Anästhesieeinheit	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*:

Anästhesieeinheit / *anesthesia unit*
APUS x3
100-300

Zweckbestimmung /
Intended Use:

Gerät zur inhalativen Verabreichung von Anästhesiegasen unter maschineller Aufrechterhaltung der Atemfunktion während eines operativen Eingriffs
Device for application of inhalative anesthetic agents maintaining automatic ventilation of the patient during a surgical treatment

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 101259 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 10 of guideline 93/42 EEC; this product is codified to class IIb.

Koblenz, Oct-09th - 2019

Torsten Kullmann
General Manager

Sascha Tietz
Product Management

Konfomitätserklärung *EC-Declaration of Conformity*		aXcent medical	
		Dok.-Nr.:	F 711-004
		Date:	09.10.2019
Projekt-Nr.:	PM-02-002	Revision:	1.2
Projekt:	Patientenmonitoringsystem	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*:

Patienten- Monitor / *Monitoring-System*
CETUS x12
200-200

Zweckbestimmung /
Intended Use:

Gerät zur Überwachung der Vitalfunktionen von Patienten
Device for monitoring of patient's vital parameters

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.*

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 101259 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 10 der Richtlinie 93/42/EWG
classification method: acc. annex IX rule 10 of guideline 93/42 EEC; this product is codified to class IIb.

Koblenz, Oct -09th - 2019

Torsten Kullmann
General Manager

Sascha Tietz
Product Management

APUS x3

Anesthesia Machine

Features

- 15.6” TFT touch screen display, integrated patient monitor as option.
- User friendly interface design and easy to operate.
- Rotatable and adjustable supporting arm.
- Full-electronic flowmeter with precise control and accurate data monitoring.
- All ventilation modes to suit neonatal, pediatric and adult patients.
- Highly integrated breathing circuit with built-in heater

axcent medical

Breathing circuit applicable for complete range

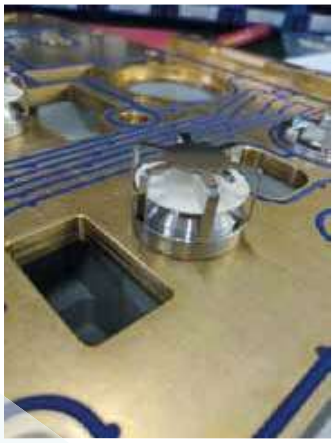
Autoclavable metal and plastic materials.
Suitable for adult, pediatric and neonatal patients.
Featured with stable pressure tightness.
Visual observation of bellows and valves.
Breathing system with ascending or descending bellows.

Reliable CO_2 absorber

One-hand operation designed CO_2 absorber. By-Pass function to ensure smooth operation. Canister detection feature.
Autoclavable PPSU material (up to 134°C)

Superior ventilator

Fresh gas, compliance and leakage compensation.
VCV, PCV, PSV, SIMV, PRVC and Manual ventilation modes.
Integrated ACGO feature to connect open circuit.



Comfortable structure

Two-sided guide rails for patient monitor, support arm and injection pump. Stainless steel material can withstand any chemical sterilization agent. Equipped with LED light to provide lighting for the large workbench.

www.axcentmedical.com

APUS x3 **Anesthesia Machine**

Specifications

axcent medical

Screen	15.6/17/19 inch TFT LED screen, 1366 x 768 pixels
Gas supply	O_2, N_2O, AIR
Vaporizer mount	Selectatec® type for two vaporizer
ACGO	Standard
Flowmeter	Electronic type – numerical and graphical
Absorber bypass	Standard
Ventilator modes	VCV, PCV, PSV, SIMV, PRVC, HLM, Manual/Spont
Tidal volume	5 – 1.500 ml
Frequency	4 – 100 bpm
I:E ratio	4:1 – 1:10
Pressure control	(PEEP+5) – 70 cm H_2O
Pressure support	(PEEP+5) – 50 cm H_2O
PEEP	Off, 3 – 30 cm H_2O
Trigger	Flow and pressure
Waveforms	Pressure-t, Volume-t, Flow-t, CO_2-t, user configurable
Spirometry loop	P-V, P-F, F-V, Reference Loop
Cylinder yoke	Optional (O_2 $N2_2$)
Battery	Standard 120 min (1 Li-Ion battery, 4800 mAh), optional 240 min (2 batteries, 9600 mAh)
AGSS	Optional
Auxiliary power outlets	3
Drawers	2
Reading lamp	LED lighting included
Gas monitor module	Optional (CO_2, AA)
Breathing circuit heater	Standard
O_2 cell	Chemical
Optional functions	BIS, NMT, Suction
Optional Patient Monitor	Integrated 15.6” monitor: ECG, SpO2, NIBP, TEMP, RESP, 2-IBP)

CETUS x12 **Patient Monitor**

Features

- 12.1" color TFT LCD screen
- 8 waveform display, up to 12-lead ECG analysis
- Useful calculation
  (Hemodynamic, Drug Dose, Oxygenation, Ventilation)
- Pacemaker detection
- ST & arrhythmia analysis
- OxyCRGs screen
- Wired/Wireless CMS, support HL7 protocol to HIS
- SpO2 pulse-tone modulation (Pitch Tone)
- MEWS (Modified Early Warning Score)
- Graphical & tabular trend review (120 hours)
- Rechargeable Lithium-Ion Battery (2600 mAh)

axcent medical

12.1”color TFT LCD screen, wide and flat screen design,ecnomic and reliable

Configuration: ECG+SpO2+NIBP+2TEMP+PR+RESP, Li-ion battery
Optional: Touch-Screen, 12-lead ECG, Masimo SpO2, 2/4/6 IBP, C.O., EtCO2, Multi-Gas, BIS, NMT, VGA, Thermal Recorder, Wired/Wireless CMS

Technical Specifications

Display

12.1” TFT (touch screen optional)
Resolution: 800 x 600
Number of traces: 8 waveforms

ECG

Lead type: 3-lead, 5-lead, 12-lead
ECG waveform: 2 channels, 7 channels, 12 channels
Display sensitivity: 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1.0), 20 mm/mV (×2.0)
Wave sweep speed: 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Bandwidth
- Diagnostic mode: 0.05 Hz~100 Hz
- Monitor mode: 0.5 Hz~40 Hz
- Surgery mode: 1Hz~20Hz
- Strong filter mode: 5 Hz~20 Hz

CMRR >100 dB
Notch: 50/60 Hz notch filter can be set to on or off
Differential input impedance >5MΩ
Electrode polarization voltage range: ±400 mV
Baseline recovery time <3s after defibrillation (in monitor and surgery mode)
Calibration signal: 1mV (peak - peak), accuracy ±3%

RESP

Measurement method: Thoracic electrical bioimpedance
Rate: 0 – 150 bpm
Measuring lead: Lead I, II
Wave gain: ×0.25, ×0.5, ×1, ×2
Respiratory impedance range: 0.5-5Ω
Baseline impedance: 500-4000Ω
Gain: 10 grades
Scan speed: 6.25 mm/s, 12.5 mm/s, 25 mm/s

Pulse Rate

Range: 30~254 bpm
Resolution: 1bpm
Accuracy: ±2bpm (non-motion)
±5bpm (motion)
Refreshing rate: 1s

TEMP

Accuracy: ±0.1 °C or ±0.2 °C °F (without probe)
Measurement range: 5~50 °C (41~122 °F)
Channel: Two channels
Resolution: 0.1 °C
Parameters: T1,T2 and TD

7-lead ECG