

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

To whom it may concern

Munich, 2020-03-06 Order No.: 713183522

Confirmation concerning certificate G1 101259 0002 Rev. 02

We confirm that the following certificate:

G1 101259 0002 Rev. 02 (EC certificate, valid until 2023-12-09)

issued to the legal medical device manufacturer:

aXcent medical GmbH Josef-Görres-Platz 2 56068 Koblenz GERMANY

covers the Directive 93/42/EEC, Annex II excluding (4) on Medical Devices with the scope:

patient monitors, anesthesia devices, ventilators, transport ventilators

and the following devices:

Product name	Model
Physiologic monitoring system for patients	PAVO
Physiologic monitoring system for patients	CETUS x12
Physiologic monitoring system for patients	CETUS x15
Physiologic monitoring system for patients	CETUS xI
Anesthesia Unit	APUS x1
Anesthesia Unit	APUS x2
Anesthesia Unit	APUS x3
Ventilator	LYRA x1
Ventilator	LYRA x2
Transport ventilator	MUSCA x1
Transport ventilator	MUSCA x2
Transport ventilator	MUSCA x3

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG - BIC
HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at www.tuv-sud.com/imprint

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With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

MÜNCHEN

The above-mentioned certificate is valid.

i.A. Randolf Köhler

TÜV SÜD PRODUCT SERVICE GMBPICT SERVICE

Medical Health Services

R. Köhler

Foreign Affairs