



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 16 04 58482 008

Manufacturer:

Foshan Anle Medical Apparatus Co., Ltd.

2 Flat, No.7, C District, Technology
& Industry Garden, Sanshui Centre

528137 Foshan, Guangdong

PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80

20537 Hamburg

GERMANY

**Product
Category(ies):**

Integral Dental Unit

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

Report No.:

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Valid from:

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Valid until:

2021-07-06

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Stefan Preiß

