



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

No. G1 103623 0002 Rev. 00

Manufacturer: Qinhuangdao Kapunuomaite Medical

Equipment S&T Co., Ltd.

2 Area, 5th Floor

No.10 Standard Workshop

Yanghe Road, Economic-Technological Development Area

066004 Qinhuangdao City, Hebei Province

PEOPLE'S REPUBLIC OF CHINA

Qinhuangdao Kapunuomaite Medical Equipment S&T Co., Ltd. Facility(ies):

2 Area, 5th Floor, No.10 Standard Workshop, Yanghe Road,

Economic-Technological Development Area, 066004

Qinhuangdao City, Hebei Province, PEOPLE'S REPUBLIC OF

CHINA

Product Category(ies): EtCO₂ Sensor.

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.

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Date. 2019-10-09

Stefan Preiß

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Head of Certification/Notified Body

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