



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 17 04 98396 002

Manufacturer:

**Wuhan Youkey Bio-Medical
Electronics Co., Ltd.**

No.3, EF, Unit 1
North Building of Xingye Building
Science and Technology Park of Wuhan University
University Park Road
East Lake Development District
430223 Wuhan, Hubei
PEOPLE'S REPUBLIC OF CHINA



EC-Representative:

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

Eiffelstraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Pocket Ultrasound System

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.:

SH17116001

Valid from:

2017-09-04

Valid until:

2022-09-03



Date, 2017-09-04

Stefan Preiß

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

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