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 078097 0007 Rev. 00

Manufacturer:

Wuxi Jike Electronics Co., Ltd.
2nd workshop floor & 3rd office floor of the 4th building
No.29 Changjiang south road
New District
214028 Wuxi, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Wuxi Jike Electronics Co., Ltd.
2nd workshop floor & 3rd office floor of the 4th building, No.29 Changjiang south road, New District, 214028 Wuxi, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Respiratory Humidifiers

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.: SH19716EXT01

Valid from: 2019-10-29
Valid until: 2024-05-26

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Prodan Sveatoslav
Date: 2021.12.13 13:36:12 EET
Reason: MoldSign Signature
Location: Moldova

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

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A4 / 07.17