



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

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 086249 0005 Rev. 01

Manufacturer

Ningbo HLS Medical Products Co., Ltd.

No. 3918-3928, Zhouxi Road, Zhouxiang Town
315324 Cixi City, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Ningbo HLS Medical Products Co., Ltd.

No. 3918-3928, Zhouxi Road, Zhouxiang Town, 315324 Cixi City,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Disposable Cervical Brush, Disposable Pap Smear Kit,
Disposable Endometrial Suction Cannula,
Disposable Oral Cavity Kits and Implements,
Disposable Gynecological Kit,
Disposable Vaginal Speculum**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

SH1982907

Valid from:

2019-12-06

Valid until:

2024-01-19

Date,

2019-12-06

Christoph Dicks
Head of Certification/Notified Body