



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 IIa, IIb or III)

No. G2 083478 0020 Rev. 02

Manufacturer:

**Zhejiang Longterm
Medical Technology Co., Ltd.**

Huancheng North Road 493
Mo Gan Mountain
National High-Tech District
313200 Deqing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, THE
NETHERLANDS

Product Category(ies):

**Hydrocolloid Blister Plaster,
Hydrocolloid Patch,
Sterile Hydrocolloid Dressing,
Wound Drainable Bag**

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.:

SH1978208

Valid from:

2019-03-30

Valid until:

2023-10-10

Date,

2019-03-30

Stefan Preiß



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Facility(ies):

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Tech District, 313200 Deqing, Zhejiang, PEOPLE'S REPUBLIC OF
CHINA