



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 029056 0067 Rev. 00

Manufacturer:

ALPRO MEDICAL GMBH

Mooswiesenstraße 9
78112 St. Georgen
GERMANY

Facility(ies):

ALPRO MEDICAL GMBH
Mooswiesenstraße 9, 78112 St. Georgen, GERMANY

Product Category(ies):

- Cleaning and disinfection preparations for water-bearing lines of medical and dental treatment units
- Cleaning and disinfection preparations for aspiration and separation systems as well as spittoon bowls of medical and dental treatment units
- Disinfection preparations for surfaces of medical products
- Preparations for cleaning and disinfection of medical and dental instruments including rotary instruments and endoscopes

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.:

713140253

Valid from:

2019-01-18

Valid until:

2023-12-31

Date,

2019-01-18

Stefan Preiß

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
 - 生产场地通过定期的监督

認證契約

認證は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとします。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認證書の有効性に関する原則的な要求事項

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
 - 定期的な工場監査を実施している

Contrato de certificação

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
 - Auditoria de monitoração realizada regularmente.



Product Service

Certificate

No. Q5 029056 0069 Rev. 00

Holder of Certificate: **ALPRO MEDICAL GMBH**

Mooswiesenstraße 9
78112 St. Georgen
GERMANY

Facility(ies):

ALPRO MEDICAL GMBH
Mooswiesenstraße 9, 78112 St. Georgen, GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Hygiene Agents, Cleaners and Disinfectants for the General Medicine, the Odontology and Laboratories as well as Special Products for the Water and Waste Water Technique in Medical Treatment Units And Dosage Devices for Decontamination Agents in Medical Devices

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713140812

Valid from: 2019-01-18

Valid until: 2021-12-31

Date, 2019-01-18

Stefan Preiß

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AlproSept-HDE/ AlproSept-HDE gel



- Dezinfectarea mâinilor, precum și dezinfectarea pielii înainte de efectuarea injecțiilor obișnuite și perforarea vaselor periferice.
- Gelul AlproSept-HDE și AlproSept-HDE au o toleranță cutanată deosebit de bună.
- Fără aldehyde și fenoli.
- Gelul AlproSept-HDE / HDE se aplică nediluat. •
- Pentru dezinfectarea igienică a mâinilor, frecați 3-5 ml AlproSept-HDE / HDE gel și mențineți umed timp de 30 de secunde.

• **Eficacitate / Aplicare**

- bactericid incl. MRSA și adecvat pentru profilaxia spitalismului
- •yeasticida (C. albicans)
- •virusul care inactivează un spectru limitat de activitate virucidă: **toate virusurile „transmise de sânge”**, precum și adeno-, rota-, noro-virusuri care nu sunt învelite
- •dovedit conform EN 1500, EN 14476
- •dezinfectarea igienică a mâinilor: 30 sec.

Ingredient activ

- Etanol, propan-2-ol, substanțe pentru îngrijirea pielii, QAC + alchilamine; HDE gel incl. agent de îngroșare

Delivery form

- **REF 5019** – 1 L AlproSept-HDE
- **REF 3014** – 1 L AlproSept-HDE gel
- **REF 4014** – 1 L Dosage pump

Accessories



REF 3519 – Distributor de perete (1 L/500 ml).

ALPRO MEDICAL GMBH • Mooswiesenstraße 9 • 78112 St. Georgen/GERMANY

To our valued
Business Partners

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6 May 2020
AH/kp

Corona virus
Information by ALPRO MEDICAL GMBH
on the efficacy of ALPRO products against the corona virus COVID-19

Ladies and Gentlemen,

Referring the last days' news focusing on corona virus infections and the resulting questions to dental professionals, we would like to clarify matters as follows.

For more than 30 years, ALPRO MEDICAL has been working on the development and production of user- and environmentally friendly hygiene products and for many years we help to maintain the health of professionals and patients.

ALPRO MEDICAL offers a wide range of products for the disinfection of hands, surfaces and instruments as well as special applications that protect against enveloped viruses including COVID-19.

Therefore we would like to inform you in the following according to the latest European regulations, which products from ALPRO MEDICAL are effective against the COVID-19 virus.

Below, please find a list of products that comply with these criteria:

For hand disinfection:

- AlproSept-HD
- AlproSept-HDE
- AlproSept-HDE gel

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Circular letter on the subject corona virus COVID-19 dated 6 May 2020

For surface disinfection:

Alcoholic:

- MinutenSpray-*classic*
- MinutenWipes 50
- MinutenWipes Jumbo 50
- MinutenWipes Maxi

Without alcohol:

- PlastiSept *eco*
- PlastiSept *eco* Wipes 50
- PlastiSept *eco* Jumbo Wipes 50
- PlastiSept *eco* MaxiWipes

General hygiene:

- DesNet +

For instrument disinfection:

- BIB forte *eco*
- AlproZyme
- WL-cid
- BC San 100

For the cleaning and disinfection of dental aspiration systems:

- AlproJet-D
- AlproJet-DD

For impression disinfection:

- PrintoSept-ID

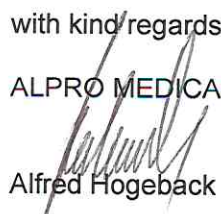
All products listed above have at least limited virucidal activity and inactivate besides bacteria all enveloped viruses. Enveloped viruses include corona and influenza viruses. All these products meet the EN 14476 standard and/or the German DVV RKI guidelines.

If you need any further information, please visit us at our website www.alpro-medical.com, use our MEDICAL PROGRAM or ask our medical device consultants.

We hope this has been helpful for you and remain

with kind regards from the Black Forest.

ALPRO MEDICAL GMBH



Alfred Hogeback