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## مجوز تولیداداره کلی تجهیزات پزشکی (Imed)

**۴1**۳۵۲۶-۶

14.4/-4/40

تدارد

تاريخ آخرين تغيير : ۱۴۰۲/۰۲/۲۵

تاريخ اعتبار :

پيوست :





## پروانه تولید وسیله پزشکی ( یک ساله )

تولید کننده : آرمان گیتی ویرا نوین

شناسه ملی: ۱۴۰۰۹۵۵۲۸۱۱

نشانی : استان مازندران – آمل – جاده هراز , کیلومتر ۵ شهرک صنعتی امامزاده عبدالله , فاز ۱ , قطعه ۲

۲

نام وسیله : دستگاه لیزر دایود

گروه تخصصی : دستگاههای پوست و موه زیبایی، ترمیمی

مدل: ARGON1200LD

نام تجاری : آرگون مدیکال حیطه کاربرد : حذف موهای زاید

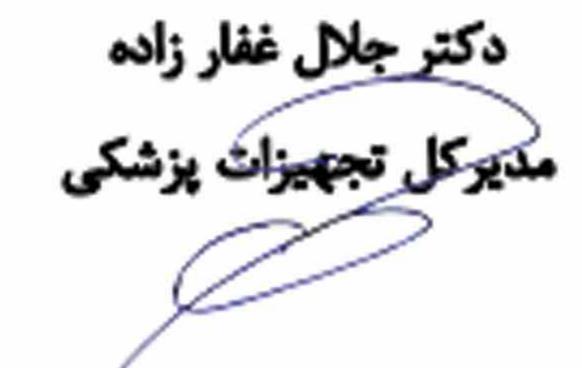
سابقه مجوز : دارد.

تعهدات و زمان اجرا : ندارد.

تعهدات اجرا نشده : ندارد.

تاييديه CE : ندارد

در اجرای بند ۱۲ ماده ۱ قانون تشکیلات و وظایف وزارت بهداشت، درمان و آموزش پزشکی مصوب ۱۳۶۷/۰۳/۰۳ و تبصره ۲ ماده ۱۴ از قانون مربوط به مقررات امور پزشکی و دارویی و مواد خوردنی و آشامیدنی با اصلاحات والحاقات بعدی مصوب ۱۳۳۴/۰۳/۲۹ ، این پروانه صرفا برای وسیله ذکر شده و با موارد قید شده در پیوست آن(در صورت داشتن پیوست) صادر گردیده است،استفاده از وسیله مذکور با توجه به حیطه کاربرد آن و شرایط مندرج در این پروانه مجاز است.در صورت عدم انجام تعهدات به جهت حفظ سلامت جامعه، پروانه تمدید نخواهد شد













Medical Device Quality Management System Certificate

### Arman Giti Vira Novin (ARGON Medical)

Headquarter: No.83, Akbari St., Yousef Abad Ave., Tehran, Iran

Site: Phase 1, Emam Zadeh Abdollah Industrial Town,

Amol, Mazandaran, Iran

has been certified in standard of Medical Device Quality Management System by U.S Certification Body in compliance with the requirements of

## ISO 13485:2016

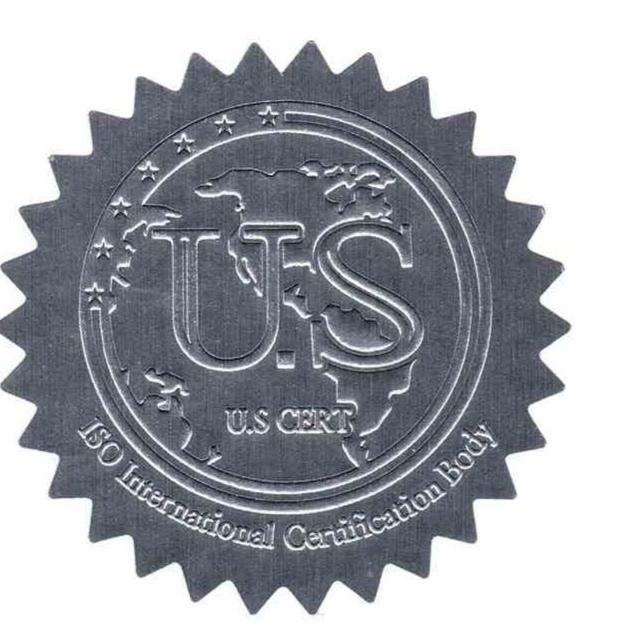
Design, Manufacturing, Sales, and After-Sale Services of Diode Laser

The U.S Certification Body verifies the status of the management system of the organization above in accordance with the international requirements through consistent assessment, and recommends its validity.

Initial Issue Date: Apr. 25. 2022

Certificate No.:

USI-2022-M-0117



President of the Certification Body

U.S Certification Body is accredited by IAS for the scope and sub scopes described in this certificate. 08393 Rm 1001-2, 16, Digital-ro 32ga-gil, Guro-gu, Seoul, Republic of Korea

(Tel: 82-2-529-8005 / E-mail: uscert@naver.com) Searching for the status of the certificate at www.usiso.org



# مجوز نمایندگی رسمی کمپانی KM



#### Weifang KM Electronics Co.,ltd

#### Letter of Authorization

2021.06.01

Subject: letter of Authorization for Arman Giti Vira Novin (ARGON) To: ISLAMIC REPUBLIC of IRAN Ministry of Health and medical Education National Medical Device Directorate TEHRAN-IRAN

We, Weifang KM Electronics Co.,ltd, as the product owner, hereby authorize Arman Giti Vira Novin (ARGON) as the Non-exclusive representative to prepare and submit appilications of the medical devices to Ministry of Health and Medical Education of Iran on our behalf.

This authorization shall apply to the following medical devices:

Diode laser machine

Arman Giti Vira Novin (ARGON) is authorized by Weifang KM Electronics for the registration, promotion, sale, distribution, marketing and service and support our products in the territory of Iran.

This authorization commences on the date of signing and is valid for 5 years from 01.06.2021 to 01.06.2026. If you have any questions, please contact us at Catherine@cavitationpl.com.

Product owner address:

WEIFANG KM ELECA

No.2656, Tongyin Street, Gaoxin Fishict, Weilang Siles nandong Province China Post Code:261061 Tel:0086-536-8885352

Authorized representative address:

No83-Akbari Street-Yousef Abad-Tehran-Iran

Tell:+982191134141 Website: Argonmeds.com

Post Code: 1434853869 Email: Info@argonmeds.com

Date: 1<sup>st</sup>, June,2021



## U.S. FOOD & DRUG Certificate



April 15, 2019

Weifang KM Electronics Co., LTD
Andy Pang
General Manager
No. 7999 Health East Street, High-tech District
Weifang, 261000 CN



U.S. FOOD & DRUG ADMINISTRATION

Re: K182924

Trade/Device Name: Diode Laser Treatment System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology

Regulatory Class: Class II Product Code: GEX Dated: March 11, 2019 Received: March 13, 2019

#### Dear Andy Pang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov

K182924 - Andy Pang

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <a href="https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm">https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm</a>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and

Radiological Health

Enclosure



# TÜV Rheinland Certificate



## Certificate



Quality Management System EN ISO 13485:2016

Registration No.:

SX 2018364-1

Organization:

Weifang KM Electronics Co., Ltd. No.7999, Health East Street, High-tech District, Weifang City

261205 Shandong

P.R. China

Scope:

Design and Development, Manufacture and Distribution of Diode Laser

Therapy Systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality

management system is subject to yearly surveillance.

Report No.: Effective date: 244291560-200

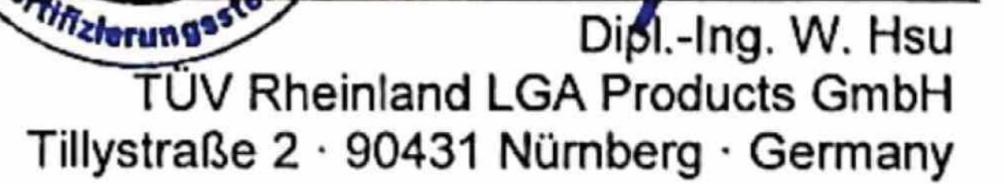
Expiry date:

2021-04-21 2024-01-28

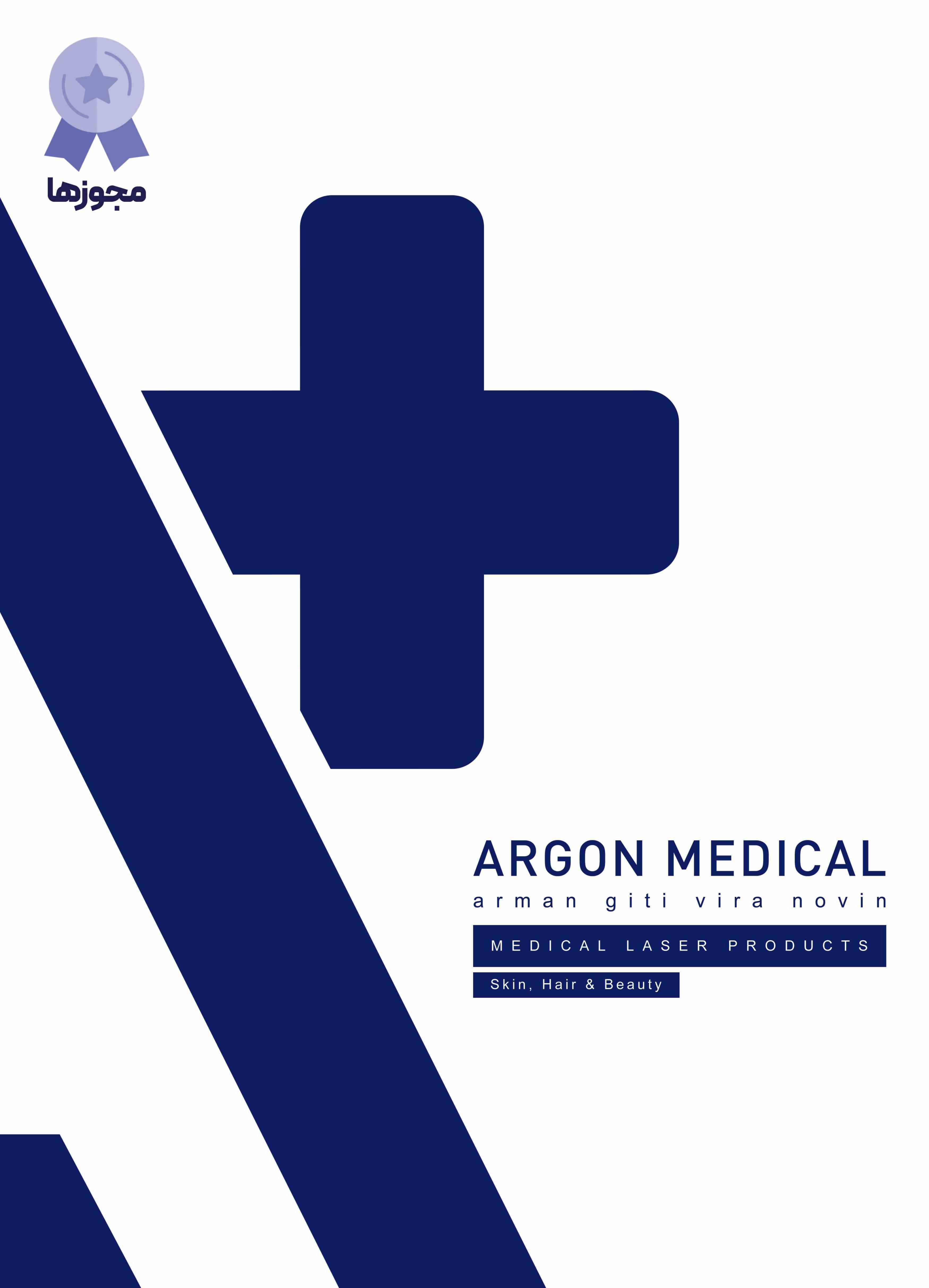
Issue date:

2021-04-21





10/020 d 04 08 @ TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approva



# TÜV Rheinland EC Certificate



#### EC Certificate



Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60126154 0001

Report No.:

15096242 001

Manufacturer:

Weifang KM Electronics Co., Ltd.

No. 7999, Health East Street

High-tech District Weifang City

261205 Shandong

China

Products:

Dermatological Diode Laser Systems

**Expiry Date:** 

2023-01-28

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date:

2018-01-29

Date:

2018-01-29



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

10/020 d C4.08 . TUV, TUEV and TUV are registered traduments. Utilisation and application requires prior approval.