

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

**Registration No.:** HD 60148506 0001

**Report No.:** 12022666 014

**Manufacturer:** Kai Industries Co., Ltd.  
1110 Oyana, Seki City  
Gifu  
501-3992 Japan

**Products:** Surgical Blades, Scalpels, Biopsy Punches, Micro Surgical Scalpels and Dental Manual Instruments

Replaces Approval, Registration No.: HD 60135210 0001

**Expiry Date:** 2023-12-19

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:** 2020-08-18

**Date:** 2020-08-18



Notified Body

  
Takashi Matsuda

**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.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60135210 0001  
**Report No.:** 12022666 012

**Manufacturer:** Kai Industries Co., Ltd.  
1110 Oyana, Seki City  
Gifu 501-3992  
Japan

Manufacturing site:  
Kai Industries Co., Ltd.  
1110 Oyana, Seki City, Gifu 501-3992, Japan

Design and Development site:  
Kai R&D Center Co., Ltd.  
1110 Oyana, Seki City, Gifu 501-3992, Japan

Sterilization Method: Gamma Irradiation  
Products, all for single use:

- Surgical Blades
- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels
- Dental Manual Instruments

Sterilization Method: Ethylene Oxide Sterilization  
Products, all for single use:

- Scalpels
- Biopsy Punches
- Micro Surgical Scalpels



**Date:** 2018-12-14

*M. Aihara*  
**M.Sc. M. Aihara**



# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Teknomek Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti.

Company Address : Halicioğlu Mah. Okumuşoğlu Sk. No:2 K:5 D:5 Beyoğlu  
ISTANBUL / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Sterile Viscoelastic solution, Methyl Cellulose - Class IIb  
- 8680548906068 / 1ml %2 / CT2S1M  
- 8680548906075 / 2ml %2 / CT2S2M  
- 8680548906112 / 1ml %2,4 / CT24S1M  
- 8680548906129 / 2ml %2,4 / CT24S2M

GMDN : 35907

Certificate Number : M.2018.106.9461  
Report Number : MD.3437.YB  
Initial Assessment Date : 02.06.2017  
Registration Date : 23.03.2018  
Recertification Assessment Date : 20.12.2019  
Reissue Date / No : 06.04.2020/01  
Revision Date /No : -  
Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class II devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY  
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76  
E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)

Technical Documentation	<b>ECG Electrodes</b>	<b>TD N 1-446</b>
<b>nissha</b> MEDICAL TECHNOLOGIES	EC Declaration of Conformity “swaromed”	<b>Issue: 002</b>
		Page 1/1

### EC Declaration of Conformity

**Manufacturer:** Nissha Medical Technologies Ltd  
Torbay Business Park, Woodview Road,  
Paignton, Devon, TQ4 7HP, UK

**Authorised Representative:** Nissha Medical Technologies SAS  
Z.A. des Boutries, 12 rue des Cayennes,  
78700 Conflans Sainte Honorine, France

**Product Group:** swaromed - ECG-Electrodes  
**GMDN Code:** 35035  
**Classification MDD:** Class I (Annex IX, Rule 1)  
**Conformity Assessment MDD:** Annex VII

**REF-numbers:** 1001, 1002, 1007D, 1008, 1008D, 1009, 1010, 1012, 1019, 1022, 1023, 1032, 1033, 1035, 1036, 1036E, 1036FT, 1037, 1037D, 1039, 1040, 1057, 1060, 1066, 1077, 1083, 1084, 1084FT, 1085, 1088, 1091, 1099, 1702, 4001, 4002, 4008, 4008D, 4009, 4010, 4019, 4022, 4023, 4036, 4036E, 4040, 4050, 4051, 4057, 4060, 4066, 4077, 4101, 4102, 4103, 4105, 4106, 4107, 4109, 4110, 4111, 4112, 4113, 4114, 4701, 4702, 4703, 4704

We hereby declare under our sole responsibility that the medical devices referenced above are in conformity with Directive 93/42/EEC (MDD) and with Directive 2011/65/EU (RoHS).

All medical devices are subject to the Quality Management System of Nissha Medical Technologies Ltd which is certified according to EN ISO 13485:2016.

The medical devices have the CE-mark.

The relevant documentation is maintained by Nissha Medical Technologies and is made available for inspection by the national authorities, the notified body and - where legally requested - by end-users and customers upon their request.

The validity of this Declaration of Conformity is in agreement with the validity period of the Quality Management System Certificate of our notified body (March 29, 2023), unless it is substituted by a new issue before this date.

Paignton, 2020-06-19



Nissha Medical Technologies Ltd.  
Daren Davies  
Quality and Regulatory Affairs Manager - UK

**Nissha Medical Technologies Ltd**  
Torbay Business Park  
Woodview Road  
Paignton  
Devon TQ4 7HP  
Tel: +44 (0) 1803 860100

File name: TDN 1-446 002 - EC Declaration of Conformity swaromed.docx	Editor: Marcel Salchner	
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