



**kai industries co., ltd.**

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## DECLARATION OF CONFORMITY

Product Group:	Surgical Instruments
General Product Group:	Micro Surgical Scalpels
Product Name:	1) Microsurgery Knife 2) Microsurgery Knife SHOSO 3) Micro Knife 4) Micro Blade 5) Safety Knife
Product List:	See the attached CE Marked Product List
Product Lot. No.:	See the shipping records (This documentation is maintained by Kai Industries Co.,Ltd.)
MDD-Classification:	Class IIa (Applied the Rule 6, Subclause 1, No Indent)
Applied Standards:	See the attached Document I
Manufacturer:	Kai Industries Co., Ltd. 1110 Oyana, Seki City, Gifu Pref., 501-3992, JAPAN
Authorized European Representative:	Kai Europe GmbH Kottendorfer Straße 5, 42697 Solingen, GERMANY

The undersigned hereby declares that the medical device as specified above conforms to the essential requirements listed in the Annex I and II of the European Medical Device Directive 93/42/EEC (MDD).

This declaration of conformity is based on

The European Medical Device Directive 93/42/EEC Annex II and is supported by a TÜV Rheinland LGA Products GmbH Notified Body (0197) Annex II Approval, with reference to articles 1 and 3 of the MDD (TÜV Rheinland LGA Products GmbH(Tillystraße 2, 90431 Nürnberg, GERMANY) Approval Registration No. HD 60148506 0001).

This Declaration of Conformity is valid in connection with the shipping records for the respective lot number of produced medical devices.

Place and Date of issue: Seki, October 21, 2020

Makoto Mori  
 Makoto Mori  
 Senior Corporate Officer,  
 Kai Industries Co., Ltd.

## Attached Document I : List of applied standards

- **EN ISO 13485:2016**
- **EN ISO 13485:2016/AC:2016**  
Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN ISO 14971:2012**  
Medical devices - Application of risk management to medical devices
- **EN 1041:2008+A1:2013**  
Information supplied by the manufacturer of medical devices
- **EN ISO 15223-1:2016**  
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
- **EN ISO 10993-1:2009/AC:2010**  
Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- **EN ISO 10993-7:2008/AC:2009**  
Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- **EN 556-1:2001/AC:2006**  
Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
- **EN ISO 11607-1:2009+A1:2014**  
Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- **EN ISO 11607-2:2006+A1:2014**  
Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- **EN ISO 11135:2014**  
Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- **EN ISO 11137-1:2015**  
Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- **EN ISO 11137-2:2015**  
Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- **EN ISO 11737-1:2006/AC:2009**  
Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- **EN 62366:2008**  
Medical devices - Application of usability engineering to medical devices
- **ISO 14644-1:2015**  
Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness

**CE Marked Product List - Micro Surgical Scalpels**

Revision No. / Date : Rev.7 / 2020-10-21

EC Certificate Registration No. : HD 60148506 0001

General Product Group : Micro Surgical Scalpels

Classification : Class IIa (Rule 6)

UMDNS Number : 15-621

Legal Manufacturer : Kai Industries Co., Ltd.

Manufacturing Facility : Kai Industries Co., Ltd. Oyana factory

R&amp;D Facility : Kai Industries Co., Ltd. Oyana factory

European Representative : Kai Europe GmbH

Allocation of all Products into Device Subcategories According to NBOG BPG 2009-3 : MD0106

Declaration of Conformity: initial Issue Date / Latest Revision : 1996-05-01 / 2020-10-21 (Rev.27)

Signature: 

Approved by: Makoto Mori, Senior Corporate Officer

A. Sterilization Method : EOG

Sterilization Facility : Kai Industries Co., Ltd. Oyana factory

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
<b>Product Name: Microsurgery Knife</b>		
A-0F	MICROSURGERY KNIFE Stab knife Angle 0° t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
A-15F	MICROSURGERY KNIFE Stab knife Angle 15° t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
A-225F	MICROSURGERY KNIFE Stab knife Angle 22.5° t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
A-30F	MICROSURGERY KNIFE Stab knife Angle 30° t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
A-45F	MICROSURGERY KNIFE Stab knife Angle 45° t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-S15	MICROSURGERY KNIFE Sideport knife Straight Angle 15° w=1.0mm t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-S30	MICROSURGERY KNIFE Sideport knife Straight Angle 30° w=1.0mm t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-S15-W07	MICROSURGERY KNIFE Sideport knife Straight Angle 15° w=0.7mm t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-S30-W06	MICROSURGERY KNIFE Sideport knife Straight Angle 30° w=0.6mm t=0.1mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-T12	MICROSURGERY KNIFE Sideport knife Trapezoid 0.5mm x 1.2mm Bevel up Anti-glare	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-T12S	MICROSURGERY KNIFE Sideport knife Trapezoid Straight 0.5mm x 1.2mm Anti-glare	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-U10	MICROSURGERY KNIFE Sideport knife Utility w=1.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-U10S	MICROSURGERY KNIFE Sideport knife Utility Straight w=1.0mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-A10	MICROSURGERY KNIFE Sideport knife Asymmetry w=1.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SP-A10S	MICROSURGERY KNIFE Sideport knife Asymmetry straight w=1.0mm	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-13AGF	MICROSURGERY KNIFE Slit knife w=1.3mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-14AGF	MICROSURGERY KNIFE Slit knife w=1.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
SLU-15AGF	MICROSURGERY KNIFE Slit knife w=1.5mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-16AGF	MICROSURGERY KNIFE Slit knife w=1.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-17AGF	MICROSURGERY KNIFE Slit knife w=1.7mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-18AGF	MICROSURGERY KNIFE Slit knife w=1.8mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-19AGF	MICROSURGERY KNIFE Slit knife w=1.9mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-20AGF	MICROSURGERY KNIFE Slit knife w=2.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-22AGF	MICROSURGERY KNIFE Slit knife w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-23AGF	MICROSURGERY KNIFE Slit knife w=2.3mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-24AGF	MICROSURGERY KNIFE Slit knife w=2.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-25AGF	MICROSURGERY KNIFE Slit knife w=2.5mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-265AGF	MICROSURGERY KNIFE Slit knife w=2.65mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-275AGF	MICROSUR2GERY KNIFE Slit knife w=2.75mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-28AGF	MICROSURGERY KNIFE Slit knife w=2.8mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-285AGF	MICROSURGERY KNIFE Slit knife w=2.85mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-30AGF	MICROSURGERY KNIFE Slit knife w=3.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-31AGF	MICROSURGERY KNIFE Slit knife w=3.1mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-32AGF	MICROSURGERY KNIFE Slit knife w=3.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLU-35AGF	MICROSURGERY KNIFE Slit knife w=3.5mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
PCB-10AGF	MICROSURGERY KNIFE Paracentesis knife w=1.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
PCT-10F	MICROSURGERY KNIFE Paracentesis knife Straight w=1.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
TR-12/14AGF	MICROSURGERY KNIFE Trapezoid knife w=1.2mm x 1.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
TR-125/14AGF	MICROSURGERY KNIFE Trapezoid knife w=1.25mm x 1.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
TR-13/15AGF	MICROSURGERY KNIFE Trapezoid knife w=1.3mm x 1.5mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
TR-14/16AGF	MICROSURGERY KNIFE Trapezoid knife w=1.4mmx1.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
TR-15/19AGF	MICROSURGERY KNIFE Trapezoid knife w=1.5mmx1.9mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-18AGF	MICROSURGERY KNIFE Clear corneal knife w=1.8mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-20AGF	MICROSURGERY KNIFE Clear corneal knife w=2.0mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-22AGF	MICROSURGERY KNIFE Clear corneal knife w=2.2mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
CCR-23AGF	MICROSURGERY KNIFE Clear corneal knife w=2.3mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-24AGF	MICROSURGERY KNIFE Clear corneal knife w=2.4mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-25AGF	MICROSURGERY KNIFE Clear corneal knife w=2.5mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-265AGF	MICROSURGERY KNIFE Clear corneal knife w=2.65mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-275AGF	MICROSURGERY KNIFE Clear corneal knife w=2.75mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-28AGF	MICROSURGERY KNIFE Clear corneal knife w=2.8mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-30AGF	MICROSURGERY KNIFE Clear corneal knife w=3.0mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CCR-32AGF	MICROSURGERY KNIFE Clear corneal knife w=3.2mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
CPU-16AGF	MICROSURGERY KNIFE Crescent knife w=1.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
CPU-22AGF	MICROSURGERY KNIFE Crescent knife Angle 45°w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
CPU-22C	MICROSURGERY KNIFE Crescent knife Angle 60°w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
CPU-26AGF	MICROSURGERY KNIFE Crescent knife w=2.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
CPD-26AGF	MICROSURGERY KNIFE Crescent knife w=2.6mm Bevel down	KH-M-TF-09-E 2020-10-21 / Rev.19
CPS-22AGF	MICROSURGERY KNIFE Crescent knife Straight w=2.2mm	KH-M-TF-09-E 2020-10-21 / Rev.19
CWD-26AGF	MICROSURGERY KNIFE Crescent knife w=2.6mm Bevel down	KH-M-TF-09-E 2020-10-21 / Rev.19
CWU-22AGF	MICROSURGERY KNIFE Crescent knife w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
CWU-26AGF	MICROSURGERY KNIFE Crescent knife w=2.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-28AGF	MICROSURGERY KNIFE Implant knife w=2.8mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-30AGF	MICROSURGERY KNIFE Implant knife w=3.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-32AGF	MICROSURGERY KNIFE Implant knife w=3.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-35AGF	MICROSURGERY KNIFE Implant knife w=3.5mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-41AGF	MICROSURGERY KNIFE Implant knife w=4.1mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-46AGF	MICROSURGERY KNIFE Implant knife w=4.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-51AGF	MICROSURGERY KNIFE Implant knife w=5.1mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-52AGF	MICROSURGERY KNIFE Implant knife w=5.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RNU-56AGF	MICROSURGERY KNIFE Implant knife w=5.6mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
VK-19GF	MICROSURGERY KNIFE 19 Gauge Vitrectomy knife Straight	KH-M-TF-09-E 2020-10-21 / Rev.19
VKB-19GF	MICROSURGERY KNIFE 19 Gauge Vitrectomy knife	KH-M-TF-09-E 2020-10-21 / Rev.19

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
VK-20GF	MICROSURGERY KNIFE 20 Gauge Vitrectomy knife Straight	KH-M-TF-09-E 2020-10-21 / Rev.19
VKB-20GF	MICROSURGERY KNIFE 20 Gauge Vitrectomy knife	KH-M-TF-09-E 2020-10-21 / Rev.19
VK-23GF	MICROSURGERY KNIFE 23 Gauge Vitrectomy knife Straight	KH-M-TF-09-E 2020-10-21 / Rev.19
VK-25GF	MICROSURGERY KNIFE 25 Gauge Vitrectomy knife Straight	KH-M-TF-09-E 2020-10-21 / Rev.19
BKS-10AGF	MICROSURGERY KNIFE Bleb knife Straight w=1.0 mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
BKB-10AGF	MICROSURGERY KNIFE Bleb knife w=1.0 mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
BKB2-10AGF	MICROSURGERY KNIFE Bleb knife 2 w=1.0 mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
KKM-18M	MICROSURGERY KNIFE KKM knife w=1.8mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
KKM-20M	MICROSURGERY KNIFE KKM knife w=2.0mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
KKM-22M	MICROSURGERY KNIFE KKM knife w=2.2mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
KKM-24M	MICROSURGERY KNIFE KKM knife w=2.4mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
KKM-275M	MICROSURGERY KNIFE KKM knife w=2.75mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
DSK-46	MICROSURGERY KNIFE DSAEK knife w=4.6mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
DSK-50	MICROSURGERY KNIFE DSAEK knife w=5.0mm Double bevel	KH-M-TF-09-E 2020-10-21 / Rev.19
MAK-22	MICROSURGERY KNIFE Arrow knife w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
AKI-29M	MICROSURGERY KNIFE Arched knife 2.9mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
AKI-32M	MICROSURGERY KNIFE Arched knife 3.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLP-20	MICROSURGERY KNIFE Slit knife Parallel side w=2.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLP-22	MICROSURGERY KNIFE Slit knife Parallel side w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLP-24	MICROSURGERY KNIFE Slit knife Parallel side w=2.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLP-28	MICROSURGERY KNIFE Slit knife Parallel side w=2.8mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLT-24	MICROSURGERY KNIFE Slit knife Triple cut w=2.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLT-265	MICROSURGERY KNIFE Slit knife Triple cut w=2.65mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLT-28	MICROSURGERY KNIFE Slit knife Triple cut w=2.8mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
SLT-30	MICROSURGERY KNIFE Slit knife Triple cut w=3.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
RV-10	MICROSURGERY KNIFE Revision slit knife w=1.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
KMU-20M	MICROSURGERY KNIFE KMU knife w=2.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
KMU-22M	MICROSURGERY KNIFE KMU knife w=2.2mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
KMU-24M	MICROSURGERY KNIFE KMU knife w=2.4mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
KMU-28M	MICROSURGERY KNIFE KMU knife w=2.8mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
KMU-30M	MICROSURGERY KNIFE KMU knife w=3.0mm Bevel up	KH-M-TF-09-E 2020-10-21 / Rev.19
GK-24	MICROSURGERY KNIFE SCLERAL KNIFE	KH-M-TF-09-E 2020-10-21 / Rev.19
<b>Product Name: Microsurgery Knife SHOSO</b>		
ST15	MICROSURGERY KNIFE SHOSO Stab knife Angle 15 ° t=0.12mm	KH-M-TF-11-E 2020-10-21 / Rev.9
ST225	MICROSURGERY KNIFE SHOSO Stab knife Angle 22.5 ° t=0.12mm	KH-M-TF-11-E 2020-10-21 / Rev.9
ST30	MICROSURGERY KNIFE SHOSO Stab knife Angle 30 ° t=0.12mm	KH-M-TF-11-E 2020-10-21 / Rev.9
SL18	MICROSURGERY KNIFE SHOSO Slit knife w=1.8mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL20	MICROSURGERY KNIFE SHOSO Slit knife w=2.0mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL22	MICROSURGERY KNIFE SHOSO Slit knife w=2.2mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL23	MICROSURGERY KNIFE SHOSO Slit knife w=2.3mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL24	MICROSURGERY KNIFE SHOSO Slit knife w=2.4mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL25	MICROSURGERY KNIFE SHOSO Slit knife w=2.5mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL265	MICROSURGERY KNIFE SHOSO Slit knife w=2.65mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL275	MICROSURGERY KNIFE SHOSO Slit knife w=2.75mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL28	MICROSURGERY KNIFE SHOSO Slit knife w=2.8mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
SL30	MICROSURGERY KNIFE SHOSO Slit knife w=3.0mm Bevel up	KH-M-TF-11-E 2020-10-21 / Rev.9
CC22	MICROSURGERY KNIFE SHOSO Clear corneal knife w=2.2mm Double bevel	KH-M-TF-11-E 2020-10-21 / Rev.9
CC24	MICROSURGERY KNIFE SHOSO Clear corneal knife w=2.4mm Double bevel	KH-M-TF-11-E 2020-10-21 / Rev.9
CC275	MICROSURGERY KNIFE SHOSO Clear corneal knife w=2.75mm Double bevel	KH-M-TF-11-E 2020-10-21 / Rev.9
CC28	MICROSURGERY KNIFE SHOSO Clear corneal knife w=2.8mm Double bevel	KH-M-TF-11-E 2020-10-21 / Rev.9
CC30	MICROSURGERY KNIFE SHOSO Clear corneal knife w=3.0mm Double bevel	KH-M-TF-11-E 2020-10-21 / Rev.9
VK20	MICROSURGERY KNIFE SHOSO 20 Gauge Vitrectomy knife Straight	KH-M-TF-11-E 2020-10-21 / Rev.9
VK20B	MICROSURGERY KNIFE SHOSO 20 Gauge Vitrectomy knife	KH-M-TF-11-E 2020-10-21 / Rev.9
<b>Product Name: Micro Knife</b>		
7512	MICRO KNIFE Angle 15 ° , 1.8mm, t=0.15mm	KH-M-TF-10-E 2020-10-21 / Rev.14
7514	MICRO KNIFE Angle 15 ° , 3.0mm, t=0.15mm	KH-M-TF-10-E 2020-10-21 / Rev.14

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
7516	MICRO KNIFE Angle 15°, 5.0mm, t=0.15mm	KH-M-TF-10-E 2020-10-21 / Rev.14
57DK	MICRO KNIFE - Hockey stick / Scleral	KH-M-TF-10-E 2020-10-21 / Rev.14
69DK	MICRO KNIFE - Sharp all around	KH-M-TF-10-E 2020-10-21 / Rev.14
EST-15/20	MICRO KNIFE - Esthetic knife w=1.5mm x 2.0mm Bevel up	KH-M-TF-10-E 2020-10-21 / Rev.14
K7512	MICRO KNIFE Angle 15°, 1.8mm, t=0.15mm	KH-M-TF-10-E 2020-10-21 / Rev.14
K7514	MICRO KNIFE Angle 15°, 3.0mm, t=0.15mm	KH-M-TF-10-E 2020-10-21 / Rev.14
K7516	MICRO KNIFE Angle 15°, 5.0mm, t=0.15mm	KH-M-TF-10-E 2020-10-21 / Rev.14
K57DK	MICRO KNIFE - Hockey stick / Scleral	KH-M-TF-10-E 2020-10-21 / Rev.14
K69DK	MICRO KNIFE - Sharp all around	KH-M-TF-10-E 2020-10-21 / Rev.14
KEST-15/20	MICRO KNIFE - Esthetic knife w=1.5mm x 2.0mm Bevel up	KH-M-TF-10-E 2020-10-21 / Rev.14
<b>Product Name: Micro Blade</b>		
7511G	MICRO BLADE Angle 15°, 1.8mm, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17
7513G	MICRO BLADE Angle 15°, 3.0mm, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17
7515G	MICRO BLADE Angle 15°, 5.0mm, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17
8513G	MICRO BLADE Angle 15°, 3.0mm curved, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17
K7511G	MICRO BLADE Angle 15°, 1.8mm, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17
K7513G	MICRO BLADE Angle 15°, 3.0mm, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17
K7515G	MICRO BLADE Angle 15°, 5.0mm, t=0.15mm	KH-M-TF-08-E 2020-10-21 / Rev.17

B. Sterilization Method: Gamma radiation

Sterilization Facility: Radia Industry Co.,Ltd.

Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
<b>Product Name: Safety Knife</b>		
SK-A0	SAFETY KNIFE Stab knife Angle0° t=0.1mm	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-A15	SAFETY KNIFE Stab knife Angle15° t=0.1mm	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-A225	SAFETY KNIFE Stab knife Angle22.5° t=0.1mm	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-A30	SAFETY KNIFE Stab knife Angle30° t=0.1mm	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU18M	SAFETY KNIFE Slit knife w=1.8mm 45° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU20M	SAFETY KNIFE Slit knife w=2.0mm 45° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17



Catalogue No. (REF No.)	Description	Technical Documentation Issue Date/ Rev.
SK-SLU22	SAFETY KNIFE Slit knife w=2.2mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU23	SAFETY KNIFE Slit knife w=2.3mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU24	SAFETY KNIFE Slit knife w=2.4mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU28	SAFETY KNIFE Slit knife w=2.8mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU30	SAFETY KNIFE Slit knife w=3.0mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-SLU32	SAFETY KNIFE Slit knife w=3.2mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR18M	SAFETY KNIFE Clear corneal knife w=1.8mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR20M	SAFETY KNIFE Clear corneal knife w=2.0mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR22	SAFETY KNIFE Clear corneal knife w=2.2mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR23	SAFETY KNIFE Clear corneal knife w=2.3mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR24	SAFETY KNIFE Clear corneal knife w=2.4mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR25	SAFETY KNIFE Clear corneal knife w=2.5mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR28	SAFETY KNIFE Clear corneal knife w=2.8mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR30	SAFETY KNIFE Clear corneal knife w=3.0mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CCR32	SAFETY KNIFE Clear corneal knife w=3.2mm 45 ° Double bevel	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CPU16	SAFETY KNIFE Crescent knife w=1.6mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CPU22	SAFETY KNIFE Crescent knife w=2.2mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-CPU26	SAFETY KNIFE Crescent knife w=2.6mm 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
SK-VKB20G	SAFETY KNIFE 20 Gauge Vitrectomy knife 45 ° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17
DSS-225/265	SAFETY KNIFE DUAL size Slit knife w=2.25 x 2.65 mm 45° Bevel up	KH-M-TF-07-R 2020-10-21 / Rev.17