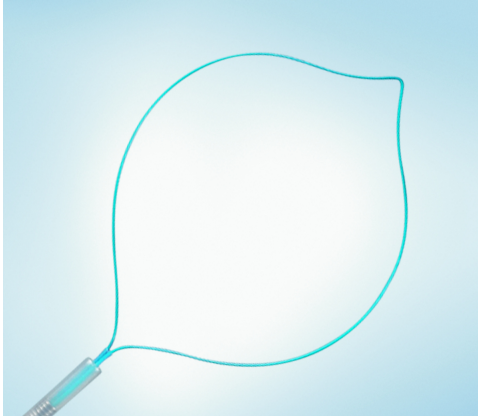


# Product-Information-Sheet

## Polypectomy, EMR and ESD

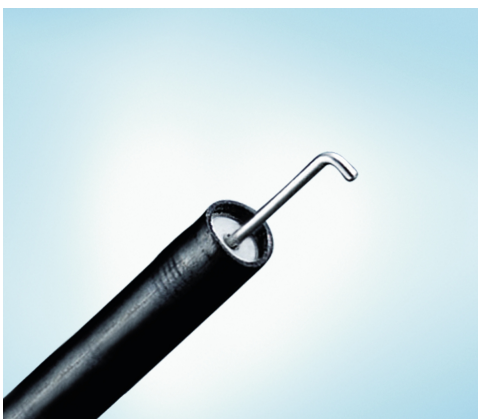
Cold and Hot  
Snares



- For polyp ligation prior to polypectomy
- Prevents postpolypectomy bleeding
- Preloaded loop, ready to use with handle
- Nylon-loop ligation keeps tissue damage to a minimum
- Opening diameter of 30 mm enables ligation of large polyps



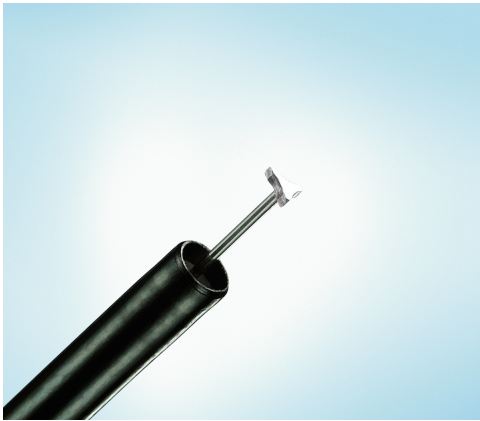
| Article number | Article Name | Quantity value | Min. working channel ø value | Working length value | Loop ø | Area Compatibility |
|----------------|--------------|----------------|------------------------------|----------------------|--------|--------------------|
| N5382130       | HX-400U-30   | 5              | ● 2.8                        | 2300 mm              | 30 mm  |                    |



- L-shaped hook for incision and dissection in longitudinal and lateral directions
- To minimise invasion, the use of a distal attachment is recommended (D-201 series) to help maintain the field of view
- Rotatable



| Article number | Article Name | Quantity value | Min. working channel ø value | Working length value | Knife length value | Features                       | Area Compatibility |
|----------------|--------------|----------------|------------------------------|----------------------|--------------------|--------------------------------|--------------------|
| N3046130       | KD-620UR     | 1              | ● 2.8                        | 2300 mm              | 4.5 mm             | Hook length: 1.3 mm; rotatable |                    |




- Triangle-tipped knife for marking, incision and dissection
- Conductive triangle tip for cutting the mucosa
- No need to rotate the knife; cutting can be performed in any direction
- Tip design suitable for controlling moderate bleeding
- To ensure a clear field of view, a distal attachment (D-201 series) may be used



| Article number | Article Name | Quantity value | Min. working channel $\varnothing$ value  | Working length value | Knife length value | Features                          | Area Compatibility |
|----------------|--------------|----------------|---|----------------------|--------------------|-----------------------------------|--------------------|
| N2119630       | KD-640L      | 1              | <span style="color: yellow;">●</span> 2.8 | 1650 mm              | 4.5 mm             | Triangle-tip plate length: 0.4 mm |                    |

## EU - KONFORMITÄTSERKLÄRUNG EC - DECLARATION OF CONFORMITY

|   |  |                            |                             |   |
|---|--|----------------------------|-----------------------------|---|
| <b>Unternehmen:</b><br><i>Company</i>   | Olympus Winter & Ibe GmbH<br>Kuehnstr. 61<br>22045 Hamburg, Germany<br>P.O.Box 70 17 09<br>22017 Hamburg, Germany<br>Telefon: +49 (40) 6 69 66-0<br>Telefax: +49 (40) 6 69 66-2109 |                            |                             |   |
| <b>Hiermit erklären wir, dass das Produkt</b><br><i>We herewith declare that the product</i>  |  |                            |                             |   |
| <b>Produktname:</b><br><i>Product name:</i>   | Siehe angehängte Produktliste /<br><i>see attached List of Related Items</i>   |                            |                             |   |
| <b>Katalog Nr./ Modellname:</b><br><i>Catalog No./ Modelname:</i>   | Siehe angehängte Produktliste /<br><i>see attached List of Related Items</i>   |                            |                             |   |
| <b>Beginnend mit Seriennummer / Lot:</b><br><i>Beginning with Serial-No / Lot:</i>  | Siehe angehängte Produktliste /<br><i>see attached List of Related Items</i>   |                            |                             |   |
| <b>Produktfamilie:</b><br><i>Product Family:</i>  | PF013 - KNIVES   |                            |                             |   |
| <b>Produktklassifizierung:</b><br><i>Product classification:</i>  | IIa  |                            |                             |   |
| <b>die Anforderungen der Medizinprodukte Richtlinie 93/42/EEC erfüllt</b><br><i>complies with the requirements of the Medical Device Directive 93/42/EEC.</i>   |  |                            |                             |   |
| <b>Diese Erklärung bezieht sich auf:</b><br><i>This declaration is based on:</i>  | Anhang II<br>Annex II  |                            |                             |   |
| Notifizierte Stellen für Produkte der Klasse Is, Im, IIa, IIb<br><i>Notified Body for products of class Is, Im, IIa, IIb:</i><br>TÜV Rheinland LGA Products GmbH – Tillystr. 2 – 90431 Nürnberg,<br>Registration- Nr/No: 0197 |  |                            |                             |   |
|   | <b>Funktion</b><br><i>Function</i>   | <b>Name</b><br><i>Name</i> | <b>Datum</b><br><i>Date</i> | <b>Unterschrift</b><br><i>Signature</i>   |
| <b>Genehmigt</b><br><i>Approved by</i>  | GM Q&R   | Martin Peters              | 2015 -10- 09                |  |

## PRODUKTLISTE LIST OF RELATED ITEMS

Diese EG-Konformitätserklärung gilt für nachfolgende Produkte

*This Declaration of Conformity covers following items:*

### PF013 – KNIVES

| Produkt Name/<br>Product Name   | REF:     | Beginnend mit:<br>Beginning with:<br>Serial-No / Lot |
|---|----------|--|
| Messer, Wellenschliff, gerade /<br>Knife, corrugated, straight  | WA35057A | 157W   |
| Messer, lanzettförmig, gerade /<br>Knife, lancet type, straight   | WA35055A | 157W   |
| Messer, halbrund, mit 5 Ch. Kanal, für A3523 /<br>Knife, semi-circular, with 5 Fr. channel, for A3523                             | O3526    | 95W  |
| Messer, lanzettförmig, für A3523 /<br>Knife, lancet type, for A3523   | O3525    | 96W  |
| Messer, halbrund, für A2523 /<br>Knife, semi-circular, for A2523  | O3524    | 96W  |
| Messer, gerade, für A37014A, steril, zur Einmalverwendung / Knife,<br>straight, for A37014A, sterile, for single use              | A37010A  | 16W 01   |
| Messer, Haken, für A37014A, steril, zur Einmalverwendung / Knife, hook,<br>for A37014A, sterile, for single use                   | A37009A  | 99277  |
| Messer, rund, für A37014A, steril, zur Einmalverwendung / Knife, round,<br>for A37014A, sterile, for single use                   | A37008A  | 991592   |
| Messer, Wellenschliff, für A3573 /<br>Knife, corrugated, for A3573  | A3577    | 92W 01   |
| Messer, halbrund, 4 Ch. Kanal, für A3573/<br>Knife, semi-circular, 4 Fr. channel, for A3573                                       | A3576    | 92W 01   |
| Messer, lanzettförmig, für A3573/<br>Knife, lancet type, for A3573  | A3575    | 96W 01   |
| Messer, halbrund, für A3573/<br>Knife, semi-circular, for A3573   | A3574    | 94W 01   |
| Messer, halbrund, flexible Spitze, für A3550/<br>Knife, semi-circular, flexible tip, for A3550                                    | A3559    | 154W 01  |
| Messer, halbrund, für A3550/<br>Knife, semi-circular, for A3550   | A3558    | 158W   |
| Messer, Wellenschliff, für A3550/<br>Knife, corrugated, for A3550   | A3557    | 159W   |
| Messer, halbrund, 4 Ch. Kanal, für A3550/<br>Knife, semi-circular, 4 Fr. channel, for A3550                                       | A3556    | 158W   |
| Messer, lanzettförmig, für A3550/<br>Knife, lancet type, for A3550  | A3555    | 157W   |
| Ersatz-Messer, für A3328/<br>Spare knife, for A3328   | A3329    | 9YW  |
| Messer, geführt/<br>Knife, guided   | A3328    | 152W   |
| Messer, flexible Spitze, lang, 2 x 355 mm/<br>Knife, flexible tip, long, 2 x 355 mm   | A2588    | 7YW  |
| Messer, 24-28 Ch., 12° und 30°, Steril, Einmalverwendung, 12 Stk./<br>Knife, 24-28 Fr., 12° and 30°, sterile, single use, 12 pcs. | A22265C  | 1YW  |
| Kürette, 24-28 Ch., 12° und 30°/<br>Curette, 24-28 Fr., 12° and 30°   | A22261A  | 1ZW  |

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

**Registration No.:** HD 60149405 0001

**Report No.:** 12018179 053

**Manufacturer:** OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho,  
Hachioji-shi, Tokyo  
192-8507 Japan

**Products:** Design and Development, Manufacture of Medical Endoscopy  
Systems, Diagnostic, Operation and Treatment Products

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144066 0001

**Expiry Date:** 2024-05-26

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:** 2020-05-12

**Date:** 2020-05-12



**Notified Body**

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

**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 60149405 0001  
**Report No.:** 12018179 053

**Manufacturer:** OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho,  
Hachioji-shi, Tokyo  
192-8507 Japan

Products included:

Medical Endoscopy Systems:

- Endoscopes
- Endotherapy Devices
- Imaging Processors
- Pumps for Endoscopy
- Light Sources
- Position Detecting Units
- Electrothermal Cautery Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units
- Electrosurgical Equipment
- Probes and Transducers for Ultrasonic Lithotriptors
- Laparoscopic Insufflators
- Ultrasound Surgical Equipment
- Ultrasonic Surgical System generator
- Ultrasonic Surgical System transducer
- Hard-tissue ultrasonic surgical system holder/tip
- Disinfecting Units
- Capsule Endoscopes and Systems
- Ultrasound Diagnostic Imaging Systems

**Date:** 2020-05-12

**Notified Body**

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

