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KEYSURGICAL
a STERIS company

Declaration of Conformity Cover Page
Deckblatt Konformitätserklärung

Key Surgical Distributes CE marked Medical Devices. Below is a list of Medical Devices in the EU that Key Surgical Distributes with the Corresponding Vendor (Manufacturer) Item Number. This document is only utilized to link the Supplier item number in the attached Declaration of Conformity with the corresponding Key Surgical Item Number.

Key Surgical vertreibt CE gekennzeichnete Medizinprodukte. Nachfolgend ist eine Liste von Medizinprodukten in der EU, die Key Surgical mit der entsprechenden Artikelnummer des Lieferanten (Herstellers) vertreibt. Dieses Dokument dient nur dazu, die Artikelnummer des Lieferanten in der beigefügten Konformitätserklärung mit der dazugehörigen Key Surgical Artikelnummer gegenüberzustellen.

Product Name	**Key Surgical Item Number**	**Vendor Item Number**	**GTIN – Include all packaging levels**
Produktname	**Key Surgical Artikelnummer**	**Lieferanten Artikelnummer**	**GTIN – Einbeziehung aller Verpackungsebenen**
Doppel-Reinigungsbürste,	EB10100	BS-B2G	Pouch: 06941991310997 Box: 16941991310994 Carton: 26941991310991
Ventil-Doppel-Reinigungsbürste	EB10101	CB100500	Pouch: 06941991310669 Box: 16941991310666 Carton: 26941991310663
Albarran Eingangsreinigungsbürste für 1mm Kanal	EB10108	CB230000	Pouch: 06941991310591 Box: 16941991310598 Carton: 26941991310595
Doppel-Reinigungsbürste 3mm mit Kugelkopf	EB10102KS	CB030317250B	Pouch: 06941991310683 Box: 16941991310680 Carton: 26941991310687
Doppel-Reinigungsbürste Bürstenköpfe: 6mm	EB10103	CB060617250B	Pouch: 06941991310577 Box: 16941991310574 Carton: 26941991310571
Doppel-Reinigungsbürste 5mm Kanal	EB10104	CBV100517230B2	Pouch:06941991310706 Box: 16941991310703 Carton: 26941991310700
Doppel-Reinigungsbürste,	EB10105	CB050517230B-C	Pouch: 06941991310720 Box: 16941991310727 Carton: 26941991310724
Bronchoskop-Reinigungsbürste 2,0mm mit Kugelkopf	EB10106KS	CBH0211120B	Pouch: 06941991310652 Box: 16941991310659 Carton: 26941991310656
Bronchoskop- Doppel-Reinigungsbürste mit 2mm	EB101062	CB020211120B	Pouch: 06941991310812 Box: 16941991310819 Carton: 26941991310816

Bronchoskop-Reinigungsbürste 2,0mm mit Kugelkopf für Biopsiekanal: ab 1,2 mm Tubus-Ø: 1,0 mm	EB101062L	CB020211230B	Pouch: 06941991310829 Box: 16941991310826 Carton: 26941991310823
Doppel-Reinigungsbürste, Länge 120cm	EB10136	CB030312120B	Pouch: 06941991318047 Box: 16941991318044 Carton: 26941991318041
Doppel-Reinigungsbürste, Einmalartikel 120cm	EB101365MM	BS-B4G	Pouch: 06941991310973 Box: 16941991310970 Carton: 26941991310977
Doppel-Reinigungsbürste, Länge 230 cm	EB10137	CB030312230B	Pouch: 06941991310676 Box: 16941991310673 Carton: 26941991310670
Koloskopie- Bürstenset, 5mm/5mm Reinigungsbürste	EB10107C	CB050517230B, CB100500	Pouch: 06941991310614 Box: 16941991310611 Carton: 26941991310618
Gastroskopie- Bürstenset, 3mm/3mm Reinigungsbürste	EB10107G	CB030317230B, CB100500	Pouch: 06941991310607 Box: 16941991310604 Carton: 26941991310601
Reinigungsbürste mit 3 Bürsten, je 6mm	EB101033	CB06060617250B	Pouch: 06941991310638 Box: 16941991310635 Carton: 26941991310632
Koloskopie- Bürstenset 3-Kopf, Reinigungsbürste	EB101033C	CB06060617250B CB100500	Pouch: 06941991310621 Box: 16941991310628 Carton: 26941991310625
Dilator Brush	EB10140	CBH0310090B	Pouch: 06941991310492 Box: 16941991310499 Carton: 26941991310496

康进 KANGJIN

Forward the health

Declaration of conformity

Manufacturer: Jiangsu Kangjin Medical Instrument Co., Ltd.
No.56, Changzheng Road, Zhenglu Town,Tianning District
213111 Changzhou City,Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA
European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80 20537 Hamburg GERMANY

SRN (Single Registration Number): CN-MF-000011142
Product Name: BRUSH FOR ENDOSCOPE CLEANING
Basic UDI: 69419913BEC3U
Product number: SEE ATTACHMENT
Classification: I
Conformity Assessment Route: Class I: EC conformity declaration according to ANNEX IV and ANNEX VIII

This declaration of conformity is issued under the sole responsibility of JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

REGULATION

General applicable regulation:
Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Place, Date of Issue: Kangjin, 2024.05.06

Signature: JIANGSU KANGJIN MEDICAL INSTRUMENT CO., LTD.
Name:
Position: President

ATTACHMENT

KS Prod. code	KJ Prod. code	Description
EB10100	BS-B2G	disposable cleaning brush Φ5-Φ10mm tube O.D.：1.7mm length：2500mm
EB10101	CB100500	disposable cleaning brush(valve cleaning) φ5-φ10mm
EB10108	CB230000	disposable cleaning brush，brush O.D.:2.3mm
EB10102KS	CB030317250B	disposable cleaning brush Φ3-Φ3mm tube O.D.：1.7mm length：2500mm
EB10103	CB060617250B	Disposable cleaning brush Φ6-Φ6mm tube O.D.：1.7mm length：2500mm
EB10104	CBV100517230B2	disposable cleaning brush (combination type)valve brush 10mm,channel brush Φ5mm, tube O.D.：1.7mm length：230mm
EB10105	CB050517230B-C	disposable cleaning brush (pipe Cleaner – Endobrushes) Φ5-Φ5mm tube O.D.：1.7mm length：230mm
EB10106KS	CBH0211120B	Disposable cleaning brush, single end cleaning brush 2mm with glue tip, with finger ring, tube O.D.：1.1mm length：1200mm
EB101062	CB020211120B	Disposable cleaning brush, double end cleaning brush 2mm with glue tip, tube O.D.：1.1mm length：1200mm
EB101062L	CB020211230B	Disposable cleaning brush, double end cleaning brush 2mm with glue tip, tube O.D.：1.1mm length：2300mm
EB10136	CB030312120B	disposable cleaning brush Φ3-Φ3mm tube O.D.：1.2mm length：1200mm
EB101365MM	BS-B4G	disposable cleaning brush Φ5-Φ5mm tube O.D.：1.2mm length：1200mm
EB10137	CB030312230B	disposable cleaning brush Φ3-Φ3mm tube O.D.：1.2mm length：2300mm
EB10107C	CB050517230B, CB100500	BRUSH KIT: 1. one CB050517230B disposable cleaning brush Φ5-Φ5mm tube O.D.：1.7mm length：2300mm with glue top 2. one CB100500 disposable cleaning brush(valve cleaning) φ5-φ10mm
EB10107G	CB030317230B, CB100500	BRUSH KIT: 1. one CB030317230B disposable cleaning brush Φ3-Φ3mm tube O.D.：1.7mm length：2300mm with glue top 2. one CB100500 disposable cleaning brush(valve cleaning) φ5-φ10mm
EB10138	CBP550517250B	Disposable cleaning brush Φ5-Φ5.5mm tube O.D.：1.7mm length：2500mm
EB101033	CB06060617250B	Disposable cleaning brush Φ6-Φ6-Φ6mm tube O.D.：1.7mm length：2500mm
EB101033C	CB06060617250B CB100500	BRUSH KIT: 1. one CB06060617250B disposable cleaning brush Φ6-Φ6-Φ6mm tube O.D.：1.7mm length：2500mm with glue top 2. one CB100500 disposable cleaning brush(valve cleaning) φ5-φ10mm
EB10140	CBH0310090B	Cleaning brush, single end cleaning brush 3mm with tip, with finger ring, tube O.D.：1.0mm length：90mm