

# 中华人民共和国医疗器械注册证

注册证编号：国械注进20142026031

注册人名称	柯惠有限责任公司 Covidien llc
注册人住所	15 Hampshire Street Mansfield MA 02048 USA
生产地址	60 Middletown Avenue, North Haven, CT 06473 USA;Building 911-67, Sabanetas Industrial Park, 00731, Ponce, Puerto Rico USA
代理人名称	柯惠医疗器材国际贸易(上海)有限公司
代理人住所	中国(上海)自由贸易试验区法赛路556号2幢102部位
产品名称	端端吻合器 EEA Autosuture Circular Stapler and EEA OrVIL Autosuture Transoral Circular Stapler Anvil
型号、规格	EEA21、EEA25、EEA28、EEA31、EEA33、EEAXL21、EEAXL25、 EEAXL28、EEAXL31、EEAXL33、EEA2135、EEA2535、EEA2835、 EEAXL2135、EEAXL2535、EEAXL2835、EEAORVIL21、 EEAORVIL25、EEAORVIL21A、EEAORVIL25A (详见附页)
结构及组成	该产品主要由器身、握把、钉砧、缝钉、环形切刀和旋转尾翼构成。端端吻合器的配件“经口钉砧输送装置”主要由输送管和钉砧组成。主要部件的材质：握把：302不锈钢；握把外壳：聚碳酸酯；钉砧：301不锈钢；环形切刀：440不锈钢；缝钉：钛（符合ASTM F67 Grade 1），穿刺器：聚碳酸酯，器身：铝；经口输送导管：聚氯乙烯。一次性使用，环氧乙烷灭菌。
适用范围	用于在开放手术或腔镜手术中全消化道端端、端侧或侧侧吻合重建术中。
附件	产品技术要求
其他内容	/
备注	原注册证编号：国械注进20142656031



审批部门：国家药品监督管理局

批准日期：二〇一四年五月十六日  
有效期至：二〇一四年五月十五日



附页：

型号、规格：

EEA 21	EEA™ AutoSuture™ circular stapler with DST series technology
EEA 25	EEA™ AutoSuture™ circular stapler with DST series technology
EEA 28	EEA™ AutoSuture™ circular stapler with DST series technology
EEA 31	EEA™ AutoSuture™ circular stapler with DST series technology
EEA 33	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL21	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL25	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL28	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL31	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL33	EEA™ AutoSuture™ circular stapler with DST series technology
EEA2135	EEA™ AutoSuture™ circular stapler with DST series technology
EEA2535	EEA™ AutoSuture™ circular stapler with DST series technology
EEA2835	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL2135	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL2535	EEA™ AutoSuture™ circular stapler with DST series technology
EEAXL2835	EEA™ AutoSuture™ circular stapler with DST series technology
EEAORVIL21	EEA™ OrVil™ Autosuture™ transoral circular stapler anvil
EEAORVIL25	EEA™ OrVil™ Autosuture™ transoral circular stapler anvil
EEAORVIL21A	EEA™ OrVil™ Auto suture™ Transoral Circular Stapler Anvil with Advancing Proximal Guide Suture

EEAORVIL25A	EEA™ OrVil™ Auto suture™ Transoral Circular Stapler Anvil with Advancing Proximal Guide Suture
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