



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	338260	Endo X - Gown, isolation, single use
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	Endo X	
<b>Postal Address</b>	141 Cranbourne Road, Frankston, VIC, 3199 Australia	
<b>ARTG Start Date</b>	23/06/2020	
<b>Product Category</b>	Medical Device Class 1	
<b>Status</b>	Active	
<b>Approval Area</b>	Medical Devices	

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

Name	Address
Hefei YuChen Plastic Products Co Ltd	North of Tuanjie Road East of Xianghe Road Feidong Economic Development Zone Hefei City, Anhui Province, China

### Products

#### 1 . Gown, isolation, single use

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	23/06/2020
<b>GMDN</b>	35492 Gown, isolation, single use		
<b>Intended Purpose</b>	A multipurpose garment, made of natural, synthetic or a combination of materials, worn by healthcare providers or visitors to isolate them from the patient. The isolation gown protects the patient from the transfer of infectious agents carried by the healthcare provider or visitor; or it can protect the healthcare provider or visitor from a contagious agent which has infected the patient. This is a disposable garment.		

### Specific Conditions

No Specific Conditions included on Record

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