SHENYUN
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PACKAGING SPECIFICATION

# Sterile Single Use Urinary Catheter

## PACKAGING LEVELS

| Level | Description | Quantity | Dimensions |
|---|---|---|---|
| **Unit package** | Paper / clear film pouch with product label | 1 pc | — |
| **Middle box** | Box | — | — |
| **Outer carton** | Corrugated carton | — | 56 × 56 × 45 cm |

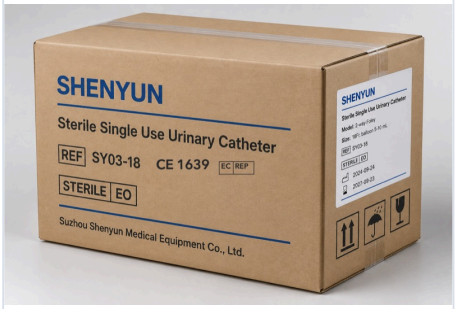
## PACKAGING IMAGES




Unit package



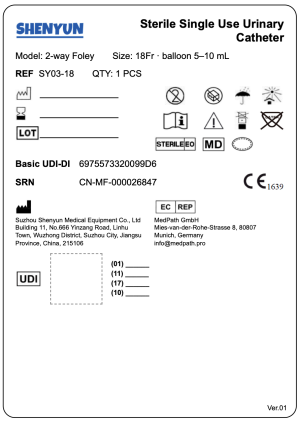

Middle box



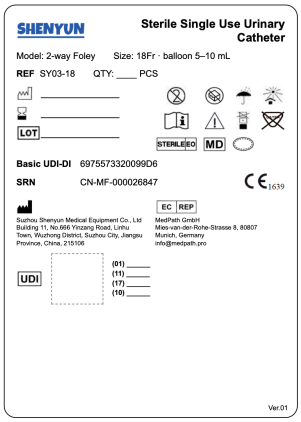

Outer carton

Packaging images are for reference only.

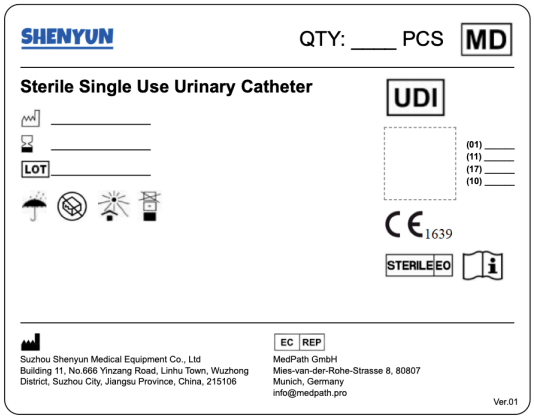
## LABEL SAMPLES




Unit label




Middle box label




Outer carton label

Label samples. Production date, expiry date, lot number and UDI are printed per batch.

## VOLUME & FREIGHT

| | |
|---|---|
| **Outer carton** | 56 × 56 × 45 cm |
| **Carton volume** | 0.141 m³ |
| **Express volumetric weight** | approx. 28.2 kg per carton (L × W × H cm / 5000) |
| **Shipping** | Express (DHL / FedEx), air or sea freight; your own forwarder is welcome |
| **Trade term** | FOB Shanghai |

## CUSTOMIZATION OPTIONS

| Item | Standard | Can be changed? |
|---|---|---|

| | | |
|---|---|---|
| **Brand / logo on box and label** | SHENYUN | Yes · SHENYUN must remain identified as the manufacturer on the label; placing on the market under the customer's name as manufacturer requires separate assessment under EU MDR |
| **Box artwork** | SHENYUN design | Yes · design service available |
| **Label language** | English | Yes · translations must meet the language requirements of the destination country |
| **Instructions for use** | English | Yes · translations must meet the language requirements of the destination country |
| **UDI / barcode** | SHENYUN UDI | Yes · customer barcode can be added; SHENYUN UDI must remain |
| **Quantity per box / carton** | As above | On request · confirmed per order |
| **Unit package material and structure** | As above | Requires regulatory assessment; may require review by the notified body (SGS, NB 1639) |
| **Regulatory information on label** | Manufacturer, certification marks, UDI, symbols | Must remain: manufacturer, EU authorised representative, CE mark with NB 1639, UDI and symbols to EN ISO 15223-1 |

This is a CE-marked Class IIa device under EU MDR (EU) 2017/745. Any change to labels, instructions for use or packaging is assessed by our regulatory department before the order is confirmed. Lead time for customized packaging is confirmed per order.

Specifications are subject to change without notice. Contact info@symedical.com.cn for the latest version.

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