



Declaration of Conformity

To Vietnam Accu-Tech JSC,

We herewith declare that

Manufacturer's Name: SEPLOU, INC.

Business Address: 203 Chandler Walk, Loganville, GA 30052, USA

Product Name:

Nalaton Catheter, latex Foley Catheter, 100% Silicone Foley Catheter, Guidewire, Ureteral Stent Set, Percutaneous Nephrostomy Set, Ureteral Access Sheath, Ureteral Catheters, Ureteral Dilator Balloon Catheters, Urodynamic Catheters, Stone Retrieval Basket, Urethral Dilators, Ureteral Dilators, Surgical Film, Surgidrape, Intermittent Catheter, Pigtail Drainage Catheter, Urine Bag, Leg & Drain Bags, Foley Insertion Tray, Endoscope Protection Cover, Catheter Insertion Kit.

Products apply to the standards as below.

Full Quality Management System Certificate Standards:

- 1 EN ISO10993-7:2008
- 2 EN ISO15223-1:2016 & EN1041:2008.
- 3 EN ISO 10993-1
- 4 EN ISO10993-5:2009
- 5 EN ISO10993-10:2010
- 6 EN ISO10993-10:2010
- 7 EN ISO 11607
- 8 EN556-1
- 9 EN ISO 13485:2016 Medical devices

Authorization Signature

Jim Griffin

July 27, 2021

Date