

Suzhou Yudu Medical Co.,Ltd

Eastern Xinzhuang (Zhangqiao) Town,215552 Changshu,China

DECLARATION OF CONFORMITY

Name and address of product owner: Suzhou Yudu Medical Co.,Ltd

Eastern Xinzhuang (Zhangqiao) Town,215552 Changshu,China

we hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the essential principles for safety and performance as laid out in the decree on medical equipment management of viet nam

Manufacturing site : Suzhou Yudu Medical Co.,Ltd

Eastern Xinzhuang (Zhangqiao) Town,215552 Changshu,China

Medical Devices :

No	Product name medical Devices	Chủng loại/ mã sản phẩm /size,model
1	Catheter Mount	Fr22,Adult,Child
2	Three way stop cock with extension tube	Length tube : 10cm,25cm,50cm,75cm,100cm
3	Suction connecting tube (Yankauer cannula)	Fr28,1/4'',3/16'' .length tube :1.8m,2m,2.5m,3m
4	Yankauer handle	With/without valve
5	Sterile Hypodermic needles for single use	18G,20G,21G,22G,23G,25G,26G .length :1' ,1x1/2',5/8'
6	Disposable sterile insulin syringe	U-100 1ml,29G,30G
7	Closed suction catheter	Fr6,8,10,12,14,16,18
8	Urethra double J catheter for single use	Fr5,6,7
9	Extension tube	30cm,75cm,140cm,150cm
10	Disposable vacuum blood collection tubes	Clot activator / sodium citrate /sodium heparin /lithium heparin /EDTA-K2 /EDTA-K3 /sodium fluoride :1,2,3,4,5,6,7,8,9,10ml
11	Stainless blood lancet	33G,32G,31G,30G,29G,28G,27G,26G,25G,24G,23G,21G,18G
12	Central venous catheter kit	Single-lumen :16G,18G,20G,22G,24G Double-lumen :Fr8,7,5,4 Triple-lumen :Fr8.5,7,5.5,4.5 Quad-lumen :Fr8.5
13	Disposable transfusion set	With/without needle
14	Dialysis tube set (blood line)	FB-A001V,A002V,A003V,A004V,A005V,A006V FB-A101V,A102V,A103V
15	Enteral feeding bag set	Single :500ml,1000ml,1200ml Double :500,1000,1200ml
16	Disposable electrode surgical pencil	HT-1,HT-2,HT-3,HT-4,HT-5,HT-6,HT-7,HT-8,HT-9,HT-10,HT-11
17	Alcohol pad	6x3cm,6.5x3cm
18	Cast padding	Width :5,7.5,10,15cm Length :2.7m,4m,4.5m
19	ECG electrode	HT-PAQ,HT-PA2-WV,HT-PB1,HT-PB1-MV,HT-PC1,HT-PC1-MV,HT-PA2,HT-PA2-MV,HT-PB2,HT-PB2-MV,HT-PC2,HT-PC2-MV,HT-PA2T,HT-PA2T-MV

Risk classification: **rule class B**

Quality management system certificate: the quality management system of Holder of certificate **Suzhou Yudu Medical Co.,ltd**

Standards applied :

ISO 13485: 2016/NS-EN ISO 13485: 2016

Certificate :246912-2017-AQ-RGC-NA-PS

This declaration of conformity is valid form 01 Jan,2022 to 30 Dec,2027

Date : 01 Jan,2022

Người đại diện hợp pháp của Chủ sở hữu

Ký tên (Ghi họ tên đầy đủ, chức danh)

Xác nhận bằng dấu hoặc chữ ký số

Legitimate representative of legal manufacturer (product owner)

Suzhou Yudu Medical Co.,ltd

Signature(Full name and title)

Confirmed by stamp or signature

