EU Declaration of Conformity

Manufacturer: JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.
Address: No.1 Baisheng Road Development Zone,Danyang,Jiangsu 212300 CHINA
SRN：CN-MF-000012834

European Representative:
Name: Metrax GmbH
Address: Rheinwaldstr. 22, 78628 Rottweil, GERMANY
SRN：DE-AR-000005481

Product Category:	Portable Phlegm Suction Unit
Model:	7E-A 7E-B 7E-C 7E-H1
Intended purpose:	Portable Phlegm Suction Unit is intended for negative pressure supply,and is used in combination with suction tubing and suction catheters to remove fluids and debris from the surgical field during surgical procedures.
Classification:	Class IIa based on MDR 2017/745 annex VIII rule 12
EMDN code：	A0601010201
Basic UDI-DI:	69332792610J5
Conformity Assessment Route:	MDR Annex IX Chapter I and Chapter III

We declare that above mentioned products meet the provision of the following EC Council Directive and Regulation. All the supporting documents and files are retained under the premises of the manufacture. We are exclusively responsible for the Declaration of Conformity. There is no applicable common specifications for Electric Suction Apparatus.
General applicable directives and regulation:
Medical Device Regulation (EU) 2017/745

Notified Body: TUV SUD Product Service GmbH

Notified Body Number: 0123

Add： Ridlerstraße 65,80339 MÜNCHEN,Germany

(EC) Certificate(s): G10 109546 0009 Rev.01

Expire date of the Certificate: 2029-03-03

Start of CE Marking: Not Yet

Signature: Jin Mei

Name: Jie Mei

Position: **Person Responsible for Regulatory Compliance**

Place: DanYang, Jiangsu, P.R.CHINA

Issue Date: Feb. 05, 2025