Declaration of Conformity

Name of Manufacturer:	Anrei Medical (HZ) Co., Ltd
Address:	No.3 Ave 8, Hangzhou Economic Development Area, 310018 Hangzhou, China
Name of EU Representative:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestra β e 80, 20537 Hamburg,Germany
Product Name:	Single Use Rotatable and Repositionable Hemoclip
Classification:	Class IIb, Rule 5
GMDN CODE	61208

Model	Specification	Model	Specification	Model	Specification
I	HA-Ⅰ-1	II	HA-Ⅱ-1	III	HA-Ⅲ-1
	HA-Ⅰ-2		HA-Ⅱ-2		HA-Ⅲ-2
	HA-Ⅰ-3		HA-Ⅱ-3		HA-Ⅲ-3
	HA-Ⅰ-4		HA-Ⅱ-4		HA-Ⅲ-4
	HA-Ⅰ-5		HA-Ⅱ-5		HA-Ⅲ-5
	HA-Ⅰ-6		HA-Ⅱ-6		HA-Ⅲ-6

Anrei's HA-I-2 equals to LPE's NLS/HC-26-230-W;

Anrei's HA-II-2 equal to LPE's NLS/HC-L-26-230-W;

Anrei's HA-III-5 equal to LPE's NLS/HC-XL90-26-230-W.

Conformity assessment route: MDD Annex II (excluding (4))

We **Anrei Medical (HZ) Co., Ltd**

No.3 Ave 8, Hangzhou Economic Development Area, China

310018 Hangzhou PEOPLE'S REPUBLIC OF CHINA

Declare under our sole responsibility that above mentioned products are in conformity with the

Medical Device Directive, MDD/93/42/EEC, amended by 2007/47/EC

Anrei Medical (HZ) Co., Ltd is exclusively responsible for Doc.

Notified Body: TUV SUD Product Service GmbH, 0123

Address: Ridlerstraße 65, 80339 München, Germany

EC Certificate Number: G1 17 08 86239 013

Start of CE marking: 2018.01.18

Place, Date of Issue: Hangzhou, Zhejiang, China

Signature:

QA Manager

2018. 6. 13

Date