

Yancheng Huida Medical Instruments Co., Ltd. CE Technical Documentation	Document No.: HD/SS-CE-03	Edition: A0	page: 1/2
	Declaration of Conformity	Effective Date: Feb-28-2018	

## EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Yancheng Huida Medical Instruments Co., Ltd.

No.2, Kuiyuan Road, Xuefu Town, Yandu District, Yancheng City, 224035  
Jiangsu, China

Name and address of the EC REP: Landlink GmbH

Dorfstrasse 2/4, 79312, Emmendingen, Germany

We declare under our sole responsibility that

the medical device:

**Surgical Needles with Non-absorbable Sutures  
(Silk Braided Non-absorbable Sutures)**

**GMDN code: 13910**

**BRAND: PRIMA**

**LOT: YHI2029 MFG: 31/05/2019 EXP: 31/05/2024**

of class:

**IIb**

according to annex IX of directive 93/42/EEC /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.  
The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure:

**Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.:

**HD 60128425 0001**

Notified Body:

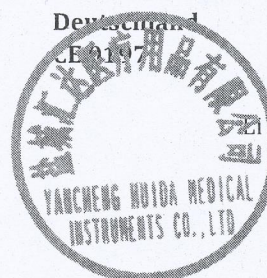
**TÜV Rheinland LGA Products GmbH  
Tillystraße 2**

**90431 Nürnberg**

**Deutschland**

**CE 0117**

Yancheng, 2018.06.25  
Place, date



Zi Bing /Technical manager  
Name and function

Signature of Zi Bing

