

Yancheng Huida Medical Instruments Co., Ltd.	Document No.: DSBCE--03	Edition: A0	page: 1/2
CE Technical Documentation	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:

Disposable Surgical Blades (with and without handle)

GMDN code: 15558

BRAND: PRIMA

of class:

II a

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.:

DD 601284260001

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Yancheng, 2018.06.25
Place, date



Li Bing /Technical manager
Name and function

Signature of Li Bing