

# EC Declaration of Conformity

**Manufacturer:**

Hoshin Medical Instrument Co., Ltd  
Rm 3-1421 Wanda Plaza, Xinbei District,  
213022 Changzhou, China

**European Authorized Representative:**

Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.  
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We, the manufacturer, herewith declare that the products: **Disposable Vaginal Mirror**  
meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to the Directive 93/42/EEC. It  
bears the mark, see att.



The product concerned has been designed and manufactured under  
a quality management system according to Annex VII of Directive 93/42/EEC.

For class I product:

Application of the above mentioned Annexes and the intervention by the Notified Body is  
limited to: the aspects of manufacture concerned with securing and maintaining sterile  
conditions.

Place, date of issue: Changzhou, Jiangsu, China, Oct 18, 2018

Signature: Zhenglin Ni

A handwritten signature in black ink, appearing to be '倪正林' (Ni Zhenglin).

