

## EC Declaration of Conformity

<i>Manufacturer:</i>	Bonraybio Co., LTD. 4F., No. 118, Gongye 9 <sup>th</sup> Rd., Dali Dist., Taichung City 41280, Taiwan (R.O.C.)
<i>European Representative:</i>	Klaus Ellensohn Torkelweg 17, 6833 Klaus, Austria
<i>Product Name:</i>	<b>Semen Quality Analyzer</b>
<i>Model:</i>	X1 PRO
<i>Brand Name:</i>	LensHooke

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to IVD General according to the Directive 98/79/EC. It bears the mark



The product concerned has been conformed with Annex III (except section 6) and met the essential requirements according to Annex I of Directive 98/79/EC.

For the evaluation regarding the product safety aspects, the following standards were applied:

**EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002  
+AC:2002, EN ISO 17511:2003, EN 13532:2002, EN ISO 15223-1:2016, EN 62366:2008, EN 62304:2006  
+AC:2008, EN 61010-1/A1:2016, IEC 61010-1:2010 COR 1:2011 + COR 2:2013, EN 61010-2-101:2017  
(IEC 61010-2-101:2015)**

The above mentioned declaration of conformity is exclusively under the responsibility of  
**Bonraybio Co., LTD.**

Taiwan (R.O.C.) 2018/08/13  
Place, date

  
Brown Hsu, CEO  
BONRAYBIO CO., LTD.  
邦睿生技股份有限公司

## EC Declaration of Conformity

<i>Manufacturer:</i>	Bonraybio Co., LTD. 4F., No. 118, Gongye 9 <sup>th</sup> Rd., Dali Dist., Taichung City 41280, Taiwan (R.O.C.)
<i>European Representative:</i>	Klaus Ellensohn Torkelweg 17, 6833 Klaus, Austria
<i>Product Name:</i>	<b>Semen Test Cassette</b>
<i>Brand Name:</i>	LensHooke

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**EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 62366:2008, EN 13975:2003, EN 13612:2002+AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13532:2002, EN ISO 15223-1:2016**


The above mentioned declaration of conformity is exclusively under the responsibility of

**Bonraybio Co., LTD.**

Taiwan (R.O.C.)

2028/08/13

Place, date



Brown Hsu, CEO  
BONRAYBIO CO., LTD.  
邦睿生技股份有限公司

## EC Declaration of Conformity

<i>Manufacturer:</i>	Bonraybio Co., LTD. 4F., No. 118, Gongye 9 <sup>th</sup> Rd., Dali Dist., Taichung City 41280, Taiwan (R.O.C.)
<i>European Representative:</i>	Klaus Ellensohn Torkelweg 17, 6833 Klaus, Austria
<i>Product Name:</i>	<b>Liquefaction Test Cup</b>
<i>Brand Name:</i>	C-KUP

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of Directive 98/79/EC which apply to them.

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The product concerned has been conformed with Annex III (except section 6) and met the essential requirements according to Annex I of Directive 98/79/EC.

For the evaluation regarding the product safety aspects, the following standards were applied:

**EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 62366:2008, EN 13975:2003, EN 13612:2002+AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13532:2002, EN ISO 15223-1:2016**


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