

EC Declaration of Conformity

<i>Manufacturer:</i>	Bonraybio Co., LTD. 4F., No. 118, Gongye 9 th Rd., Dali Dist., Taichung City 41280, Taiwan (R.O.C.)
<i>European Representative:</i>	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany
<i>Product Name:</i>	Sperm Separation Device
<i>Model:</i>	CA0, CA1
<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 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 62366:2008, EN 13975:2003, EN ISO 23640:2015, EN ISO 15223-1:2021

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

Bonraybio Co., LTD.

Taiwan (R.O.C.)

Place, date

2022/01/27



Brown Hsu, CEO