

## EC Declaration of Conformity

<b>Manufacturer:</b>	Bonraybio Co., LTD. 4F., No. 118, Gongye 9 <sup>th</sup> Rd., Dali Dist., Taichung City 41280, Taiwan SRN :
<b>European Representative:</b>	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany SRN: DE-AR-000005430
<b>Product Name:</b>	LensHooke X QC Beads (For Semen)
<b>Intended purpose</b>	The LensHooke <sup>®</sup> X QC Beads (For Semen) are supplied as three different levels of control and it has been developed as a tool to assess the accuracy and precision of laboratory's sperm counting methods by providing a known target value and +/- range.
<b>Product class / Rule</b>	Class A / Rule 5
<b>Trade name/Model/Basic UDI-DI:</b>	Please check ANNEX

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of Regulation 2017/746 which apply to them.  
The medical device has been assigned to the Regulation 2017/746. It bears the mark



Following the requirements relating to the EC Declaration of Conformity set out in Regulation 2017/746.

For the evaluation regarding the product safety aspects, the following standards were applied:  
**EN ISO 13485:2016, EN ISO 14971:2019, ISO/TR 24971:2020, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 13612:2002 +AC:2002, EN ISO 17511:2021, EN 13532:2002, EN ISO 15223-1:2021, EN 62366-1:2015, EN ISO 23640:2015**

### ANNEX

Item	Trade Name	Product Name	Product Model	Basic UDI-DI
1	LensHooke	X QC Beads (For Semen)	X QC Beads	471987474QX0T6

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

**Bonraybio Co., LTD.**

Taiwan 2022. 02. 24  
Place, date

  
YJ Liao, Executive Vice President