

## 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 SRN :
<i>European Representative:</i>	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany SRN: DE-AR-000005430
<i>Product Name:</i>	Semen Analysis System
<i>Intended purpose:</i>	The LensHooke® X12 PRO Semen Analysis System (For Professional) used with LensHooke® Sperm DNA fragmentation test kit (SCD assay) and LensHooke® Sperm double strand DNA fragmentation test kit (SDFR assay) is an optical device for human semen analysis which provides direct and calculated quantitative measurement for Sperm DFI (DNA Fragmentation Index, %). The LensHooke® X12 PRO Semen Analysis System (For Professional) does not provide a comprehensive evaluation of a male's fertility status, and is intended for in-vitro diagnostic use. Only for Professional use.
<i>Brand Name/Model/Basic UDI-DI:</i>	Please check ANNEX
<i>Product class / Rule</i>	Class A, Rule 5

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 IVD General according to the Regulation 2017/746. It bears the mark



Following the procedure 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 17511:2003, EN ISO 15223-1:2016, EN 62366-1:2015, EN 62304:2006 +A1:2015, EN 61010-1:2010/AMD1:2016, EN 60601-1-2:2015+A1:2021, EN 61000-3-2:2019, EN 61000-3-3:2013+A1:2019, EN 61326-1:2013, EN 61326-2-6:2013

### ANNEX

Item	Brand Name	Product Name	Product Model	Basic UDI-DI
1	LensHooke	Semen Analysis System	X12 PRO	471987474X12QT
2		Sperm DNA Fragmentation Test Kit (SCD Assay)	R10	471987474R10PR
3		Sperm Double Strand DNA Fragmentation Test Kit (SDFR assay)	R11	471987474R11PT

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

**Bonraybio Co., LTD.**

Taiwan (R.O.C.) 2022/01/11

Place, date

  
 \_\_\_\_\_  
 Brown Hsu, CEO