CE

MICROPTIC
AUTOMATIC DIAGNOSTIC SYSTEMS

EC- DECLARATION OF CONFORMITY

We herewith declare that the following In Vitro Diagnostic Medical device meet the transposition into national law Royal Decree 1662/2000, the provisions of Council Directive 98/79/EC of 27 October 1998 In vitro diagnostic directive. All supporting documentation is retained at the premises of the manufacturer.

Manufacturer: MICROPTIC S.L.
Av. Josep Tarradellas 8, 1º 6ª
08029 - Barcelona (Spain)

Generic Name: **SCA System**

Product Name: - Sperm Class Analyzer- SCA (CASA system)
- Automatic Sperm Class Analyzer- SCA SCOPE (CASA system)

Directives: In vitro diagnostic Directive
(Annex III – Self declare) 98/79/EC

Classification: Other General Device

Date: 04/02/2019

Standards:

ISO 9001:2015	(Quality Management)
ISO 13485:2016	(Design, Production, Installation and Servicing)
EN 62304:2006	(Medical Device Software)
EN ISO 15223-1:2016	(MD symbols)
EN ISO 18113-3:2009	(IVD labelling)
EN 61010-2-101	(Safety for IVD)
EN ISO 14971:2012	(Risk Management to Medical Devices)
EN 62366:2008	(Usability)
EN 62304:2006/AC2008	(Update)
EN 61326-2-6:2006	(IVD medical equipment IEC)

Responsible person, position in company:

Jose Antonio Bellver Gascón, General Manager

Signature:

Digitally signed by Rusu Ghenadie
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