



**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:** **Sperm Analyzer**

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

**Classification:** Not listed A or B, Article 9 – (Self declare)

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

**Classification:** Other General Device

**Date:** 30/03/2020

**Standards:** ISO 9001:2015 (Quality Management)  
ISO 13485:2016 (Design, Production, Installation and Servicing)  
EN 62304:2006/A1:2015 (Medical Device Software)  
EN 62304:2006/AC2008 (Medical Device Software, update)  
EN ISO 15223-1:2016 (MD symbols)  
EN ISO 18113-3:2009 (IVD labelling)  
EN 61010-2-101:2017 (Safety for IVD)  
EN ISO 14971:2012 (Risk Management to Medical Devices)  
EN 62366:2008 (Usability)

**Responsible person, position in company:**

Eduard Sánchez Malloí, CEO

Signature:

  
**MICROPTIC S.L.**  
Av. Josep Tarradellas, 8, 1º 6ª  
08029 Barcelona (Spain)  
T. 93 419 29 10 - F. 93 419 94 26