



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 SCOPE**

Product Name: 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: 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 Mallol, CEO

Signature:

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