	Declaration of Conformity	TF-001 Revision: F Date: 11/23/2015

I. **Manufacturer**:
Sunlight Medical, Inc. 5570 Florida Mining Blvd S., Suite 603, Jacksonville, FL 32257.

II. **Authorized Representative**:
RMS-UK Limited, 28 Trinity Road, Nailsea, Somerset, BS4 8 4NU, England.

III. **Quality System**:
The quality management system of the manufacturer has been approved by National Standards Authority of Ireland (NSAI) according to EN ISO 13485:2003+AC: 2012. The sterilization of the products (sterile function of the pipettes) has been approved by the notified body NSAI according to Directive 93/42/EEC Annex V.

IV. **Notified Body**:
National Standards Authority of Ireland, 1 Swift Square, Northwood Santry, Dublin 9, Ireland.
NB #0050.

V. **Classification**: Class Is.

VI. GMDN Code: 38522

VII. **Product(s):** Pipettes (See attached list)

VIII. **The Product(S) Listed Above Is In Conformance With The Standards Listed Below**:

ISO 11607-1:2009	Packaging materials and systems for medical devices which are to be sterilized – Part I: General requirements.
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices.
ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied.
ISO 11137-1:2006/A1: 2013	Sterilization of healthcare products – Radiation - Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	Sterilization of health care products. Radiation. Establishing the sterilization dose
EN ISO 13485:2003 /AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes.

We, the manufacturer, hereby declare that the medical devices listed above conform to the applicable provisions of EC Directive 93/42/EEC Annex V, concerning medical devices. Certificate Registration No. 252.944.

IX. **Expiration Date**: 2017-09-23

Name / Title Dunsong Yang/ President

11/25/2015
Date

SUMMARY TABLE OF PROPOSED PIPETTES

TYPE OF PIPETTE	CATALOGUE NUMBER	DIMENSSIONS	ANGULA-TIONS	Variations	INTENDED USE
Intracytoplasmic Sperm Injection (ICSI) Injection Pipette	SIC-45V-xxL(-U)	OD: 6 µm ID: 4-4.5 µm	0^0 - 45^0	Short taper Spiked	To inject a single sperm into an oocyte
	SIC-45H-xx(-U)	OD: 6 µm ID: 4-4.5 µm	0^0 - 45^0	Long taper spiked	
	SIC-45W-xxL(-U)	OD: 6 µm ID: 4-4.5 µm	0^0 - 45^0	Strong taper Spiked	
	SIC-45T-xxL(-U)	OD: 6 µm ID: 4-4.5 µm	0^0 - 45^0	Long taper Non-spiked	
	SIC-45N-xxL(-U)	OD: 6 µm ID: 4-4.5 µm	0^0 - 45^0	Short taper Non-spiked	
	SIC-50V-xxL(-U)	OD: 7 µm ID: 4.5-5 µm	0^0 - 45^0	Short taper Spiked	
	SIC-50H-xx(-U)	OD: 7 µm ID: 4.5-5 µm	0^0 - 45^0	Long taper Spiked	
	SIC-50W-xxL(-U)	OD: 7 µm ID: 4.5-5 µm	0^0 - 45^0	Strong taper Spiked	
	SIC-50N-xxL(-U)	OD: 7 µm ID: 4.5-5.0 µm	0^0 - 45^0	Short taper Non-spiked	
	SIC-55V-xxL(-U)	OD: 7 µm ID: 4.5-5 µm	0^0 - 45^0	Short taper spiked	
	SIC-55H-xx(-U)	OD: 7 µm ID: 5-5.5 µm	0^0 - 45^0	Long taper Spiked	
	SIC-55W-xxL(-U)	OD: 7 µm ID: 5-5.5 µ	0^0 - 45^0	Short taper Spiked	
	SIC-55N-xxL(-U)	OD: 7 µm ID: 5-5.5 µm	0^0 - 45^0	Short taper Non-spiked	
Spermatid Injection Pipette	SIC-70W-xx	OD: 9 µm ID: 6.5-7.5 µm	0^0 - 45^0	Short taper Spiked	To inject an immature sperm cell (spermatid) into an oocyte
	SIC-90W-xx	OD: 11µm ID: 8.5-9.5 µm	0^0 - 45^0	Short taper Spiked	
	SIC-100W-xx	OD: 12µm ID: 9.5-10.5 µm	0^0 - 45^0	Short taper Spiked	
	SIC-120W-xx	OD: 14µm ID: 11-12 µm	0^0 - 45^0	Short taper Spiked	
Holding pipette	SHP-70-xx	OD: 70-79 µm ID: 15-20 µm	0^0 - 45^0	N/A	To hold an oocyte or embryo in position during ICSI and other micromanipulation procedures
	SHP-70S-xx	OD: 70-79 µm ID: 10-15 µm	0^0 - 45^0	N/A	
	SHP-90-xx	OD: 90-99 µm ID: 15-20 µm	0^0 - 45^0	N/A	
	SHP-100-xx	OD: 100-120 µm ID: 15-20 µm	0^0 - 45^0	N/A	
	SHP-120-xx	OD: 121-130 µm ID: 15-20 µm	0^0 - 45^0	N/A	

	SHP-130-xx	OD: 131-140 µm ID: 15-20 µm	0^0 - 45^0	N/A	
	SHP-150-xx	OD: 141-160 µm ID: 15-20 µm	0^0 - 45^0	N/A	
	SHP-120B-xx	OD: 121-130 µm ID: 25-30 µm	0^0 - 45^0	N/A	
	SHP-120D-xx	OD: 121-130 µm ID: 30-40 µm	0^0 - 45^0	N/A	
	SHP-130B-xx	OD: 131-140 µm ID: 25-30 µm	0^0 - 45^0	N/A	
	SHP-150B-xx	OD: 141-160 µm ID: 25-30 µm	0^0 - 45^0	N/A	
	SHP-180B-xx	OD: 170-180 µm ID: 25-30 µm	0^0 - 45^0	N/A	
Zona Drilling Pipette	SZD-10-xx SZD-10D-xx	OD: 12-14 µm ID: 8-10 µm	0^0 - 45^0	Flat tip	To apply acidic solution or enzyme onto the zona pellucida (the outer shell) of an oocyte, thus creating a hole on the zona and assisting an embryo in hatching prior to implantation.
	SZD-12-xx SZD-12D-xx	OD: 13-15 µm ID: 10-12 µm			
Partial Zona Dissection (PZD) Pipette	SPD-xx	thin taper with a closed, sharp point	0^0 - 45^0	N/A	To cut an opening on the zona of an oocyte mechanically in assisting embryo hatching prior to implantation.
Denuding Pipette	SDP-120	120-124 µm	0^0	Unpolished tip	> To remove cumulus cells attached to the zona prior to micromanipulation procedures and fertilization assessment
	SDP-125	125-129 µm			
	SDP-130	130-134 µm			
	SDP-140	135-144 µm			
	SDP-150	145-154 µm			
	SDP-160	155-164 µm			
	SDP-170	165-174 µm			
	SDP-180	175-184 µm			
	SDP-70P	65-74 µm	0^0	Polished tip	> To transfer cells, oocytes and embryos from one dish to another during other assisted reproduction procedures.
	SDP-80P	75-84 µm			
	SDP-90P	85-99 µm			
	SDP-100P	100-119 µm			
	SDP-120P	120-139 µm			
	SDP-140P	140-159 µm			
	SDP-160P	160-189 µm			
	SDP-190P	190-219 µm			
	SDP-220P	220-249 µm			
	SDP-250P	250-289 µm			
	SDP-290P	290-319 µm			
	SDP-320P	320-349 µm			
	SDP-350P	350-380 µm			

Polar Body Biopsy Pipette	SPB-15Z-xx SPB-15X-xx SPB-15S-xx	ID: 13-15 µm	0^0 - 45^0	Z--flat X—beveled S--spiked	To remove polar bodies from human oocyte and embryo for PGD
Blastomere Biopsy Pipette	SBB-20Z-xx	ID: 18-22 µm	0^0 - 45^0	Z--flat X—beveled	To remove blastomeres or trophectoderm cells from human embryo for PGD
	SBB-25Z-xx	ID: 23-27 µm			
	SBB-30Z-xx	ID: 28-32 µm			
	SBB-35Z-xx	ID: 33-37 µm			
	SBB-40Z-xx	ID: 38-42 µm			
	SBB-20X-xx	ID: 18-22 µm			
	SBB-25X-xx	ID: 23-27 µm			
	SBB-30X-xx	ID: 28-32 µm			
	SBB-35X-xx	ID: 33-37 µm			
	SBB-40X-xx	ID: 38-42 µm			

Notes: xx – representing angulations changes
L – when ‘L’ is added after ‘xx’ it represents a tip-to-elbow length of 1.0mm.
U – representing ICSI pipette that is bent with the opposite direction for left hand operation.
H – represents ICSI pipette with tip to elbow length is 750µm, other pipette has the tip to elbow length 550 µm.
D – represents longer parallel wall in tip section with zona drilling pipettes.