

Declaration of Conformity

Application of Council Directive(s): Low Voltage Directive 2014/35/EU
Machinery Directive 2006/42/EC
Electromagnetic Compatibility Directive 2014/30/EU

Manufacturer's Name: CooperSurgical, Inc.

Manufacturer's Address: 95 Corporate Drive, Trumbull, CT 06611

Standards to which Conformity is Declared: IEC 61010-2-010:2003, IEC 61010-1:2010 (3rd Edition)

Type of Equipment: In-Vitro Fertilization (IVF) Workstations and Laminar Airflow (LAF) Cabinets

Model Numbers: Fortuna Series - Refer to Page 2 for a list of all model numbers

Date of First Issue: November 07, 2014

We hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Rev. A: First Issue. Nov. 7, 2014
Rev. B: Update Low Voltage and Electromagnetic Compatibility Directives to the current versions (LVD 2014/35/EU and EMCD 2014/30/EU). Remove P/Ns WF900L, WF1200L, WF1500RL, WF1500LL, WF1800RL, WF1800LL, WF1800DL, and WF1800MPL – discontinued models. Feb 3, 2017

 July 10, 2018
(Signature) (Date)

J. Chris Jensen
(Full Name)

Senior Director, Regulatory Affairs & Compliance
(Position)

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Fortuna In-Vitro Fertilization (IVF) Workstations

Ref. Number	Description
WF900E	Fortuna 900 IVF
WF1200E	Fortuna 1200 IVF
WF1500RE	Fortuna 1500 IVF
WF1500LE	Fortuna 1500 IVF
WF1800RE	Fortuna 1800 IVF
WF1800LE	Fortuna 1800 IVF
WF1800DE	Fortuna 1800 DUAL HEAT
WF1800MPE	Fortuna 1800 MULTI ELEC
WF1200ICSI	Fortuna 1800 ICSI

Fortuna Laminar Airflow (LAF) Cabinets

Ref. Number	Description
WF900	Fortuna 900 LAF
WF1200	Fortuna 1200 LAF
WF1500	Fortuna 1500 LAF
WF1800	Fortuna 1800 LAF