

## Declaration of Conformity

### Manufacturer:



Thermo Fisher Scientific  
LSP - Rochester  
75 Panorama Creek Drive  
Rochester NY 14625-2385  
USA  
Phone: +1-585-586-8800

### Authorized European Representative:



Nunc A/S  
Thermo Fisher Scientific  
Kamstrupvej 90  
PO Box 280  
DK-4000 Roskilde  
Denmark  
Phone: +45 4631 2000

### Product:

Name(s): IVF Center Well Dish, MEA Certified  
IVF ICSI Dish, MEA Certified  
Catalog Number / 150260  
Reference Number: 150265



### Conformity Assessment Route:

This device was assessed in conformance with Annex II (Full quality assurance system) of European Council Directive 93/42/EEC concerning medical devices, as amended.

I herewith declare that the abovementioned product fulfills the Essential Requirements of EU Directive, 93/42/EECC (Medical devices, dated June 14, 1993), Annex I, as amended. The device was assessed in conformance with Annex II (Full quality assurance system) of EU Directive, 93/42/EECC (Medical devices, dated June 14, 1993), as amended.

All supporting documentation is retained under the premises of the manufacturer.

**Notified Body:**

DGM (Danish Medical Devices Certification)  
DS Certification A/S / DGM  
Kollegievej 6  
2920 Charlottenlund  
Denmark  
Phone: +45 72 24 59 00

**(EC) Certificate**

DGM-687

**Start of CE-Marking**

2010-03-19 on Lot number: 1006803

**Place & Date of Issue**

Rochester, NY, USA on 2010-03-19

Signed: \_\_\_\_\_



date: 3/22/2010

On behalf of Nalge Nunc international, Robert Prescott  
Manager, Regulatory Affairs and Quality Assurance  
Thermo Fisher Scientific