

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