



DECLARATION OF CONFORMITY

We,

NUNC A/S
Kamstrupvej 90,
DK-4000 Roskilde
Denmark

part of Thermo Fisher Scientific,

hereby declare that the following NUNC IVF Petri Dish products:

Item no.	Product name and description
150255	NUNC IVF Petri Dish 35*10mm
150270	NUNC IVF Petri Dish 60*15mm
150360	NUNC IVF Petri Dish 90*17mm

Are classified as class IIa products in accordance to rule 2 of Annex IX and fulfills the Essential Requirements of Annex I of the EU Directive 2007/47/EC amending Directive 93/42/EEC.

Furthermore, the design and production of the listed products complies with the relevant parts of the DS/EN ISO 13485:2012 including the DS/EN ISO 13485:2012/AC2012.

The notified body, DS Certificering A/S (DGM) – identification no. 0543, has performed an inspection and approved the quality system of NUNC A/S in conformity with the requirements of with Annex V, section 3.2 – Production quality assurance, of Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law. Based on the inspection the certificate DGM-693 was subsequently issued, valid from 2010-05-05.

The notified body, QMI-SAI Canada Limited, has performed an inspection and certifies that the Quality Management System of NUNC A/S complies with the requirements of ISO 13485:2003 and subsequently issued the certificates CERT-0044731 (CMDCAS) and CERT-0044732, both valid from 2010-04-05.

Signed for and on behalf of Nunc A/S:

Signature:


Cecilie Hurup Hansen, QA/RA Specialist

Date:

2012-11-12
(YYYY-MM-DD)