Thermo Fisher Scientific
Nunc A/S
Kamstrupvej 90, P.O. Box 280
DK-4000 Roskilde, Denmark
+45 4631 2000 Tel
Info.nunc@thermofisher.com
AS 24482 VAT/SE NO. DK 39582910
www.thermoscientific.com

CE

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 Tissue Culture 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 medical devices class IIa, as per conformity route for device classification stated in the Medical Device Directives 93/42/EEC amended by 2007/47/EEC, Annex IX, section III. Classification, Rule 2, and meet the Essential Requirements set out in the mentioned Directives.

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.

Conformity Assessment Route:
The notified body no. 0543, Presafe Denmark A/S, located in Denmark, Tuborg Havnevej 8, 2900 Hellerup, has performed inspection and approved the quality system of NUNC A/S in conformity with the requirements outlined in the Annex V, section 3.2 – Production quality assurance, of the Medical Device Directive 93/42/EEC as transposed into the Danish Law.

The notified body has confirmed compliance of the company activities and the CE-marked medical devices with the regulatory requirements, and issued the Quality System Certificate – DGM 770, and the EC certificate – DGM 693, initial date of issue 2010-04-27.

Signed for and on behalf of Nunc A/S:

Signature: _____
Anne-Mette Reimann, QA Manager

Date: 2016-06-22
(YYYY-MM-DD)