

EC DECLARATION OF CONFORMITY

MICRO WELL GROUP CULTURE DISH

Manufacturer

Vitrolife A/S

Jens Juuls Vej 20 DK-8260 Viby J

Denmark

Conformity assessment procedure

Annex VII combined with Annex V of the Medical

Device Directive 93/42/EEC

Product category

IVF culture dish

Product

Micro well group culture dish, 9 well

Micro well group culture dish, 16 well

Product code

16604

16606

Classification

Class IIa according to Annex IX, rule(s) 2

Certificate(s)

DGM-673

Notified Body

Presafe Denmark A/S

Tuborg Parkvej 8 DK-2900 Hellerup

Denmark

Notified Body identification No.

0543

We, the manufacturer hereby declare that the above mentioned products comply with the European Medical Device Directive 93/42/EEC and its relevant transposition into the national laws of the European member states into which countries we place the devices.

12 L Welle March 24, 2017

Signed in Viby J:

Name and authority

Henrik Wahlgren, QA Manager