

Godkendt af: Approved by:	rosber	Dato: Date:	2011-03-17	Revisionsnr.: Revision No.:	14-b
Frigivet af: Released by:	QA	Dato: Date:	2011-04-12	CO nr./No.:	CO-3861
Gyldig fra/valid from: 2011-04-12				Side/page 1 af/of 5	

1 Product name:

Thermo Scientific Nunc UpCell 48 MultiDish, with lid.

1.1 Catalogue No.:

1 74898

1.2 Raw material.:

1 50687

2 Intended use:

The product surface must be thermo-responsive. The cell culture must detach by lowering temperature. From 37°C to less than 32°C.

The product is for < research use only>.

The product is for single use only.

Description:

2.1 Surface:

The surface is responsive to temperature reduction with a minimum cell detachment ratio >50% when using SWISS 3T3 albino.

At no time from the unpacking of the Nunc Brand product to the time of surface treatment of CellSeed, may the inside of the well surface be touched by anything. This will damage the surface treatment from Thermo Fisher Scientific, Roskilde Site.

2.2 Sterility:

The product has a level of sterility of minimum SAL 10⁻⁶.

3 Quality control:

PNIPAM surface has been uniformly applied. Uniformity is not inspected physically on usual QC. (QC conducted only by cell culture testing).

No visible spots, scratches, dust and finger marks. Please see the enclosed photos.

The product has to be non-pyrogenic.

For further information, please see the quality agreement.

4 Storage and handling:

During storage, handling and transportation:

The product temperature has to be between -20°C and +60°C.

The humidity has to be within a range that ensures no damage of product or packaging.

No direct sunlight.

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Gyldig fra/valid from: 2011-04-12				Side/page 2 af/of 5	

5 Packaging:

5.1 The primary bag, as well as the boxes, is labelled with product name, Catalogue No., LOT No., <research use only>, <do not re-use>, <store at room temperature>, sterile period and shelf-life period according to the labels shown below. Top label and front label are also printed with quantity in bag/case. The labels are placed in such way, that they are readable in the same direction for both product and bag.

Top label 148.5x105 mm

Front label 91x55 mm

Sterilization label 63.5x38.1mm

5.2 Primary packaging:

The plate is assembled with lid.

One plate in each primary bag.

The primary packaging has to keep the product sterile.

The primary packaging has to diffuse the gas and steam from process after sterilization.

Tear indication at the bag.

Without our approval, the primary packaging cannot be changed.

5.3 Secondary packaging – inner box:

User protocol applies to each secondary case – the inner box.

6 plates in each secondary case – inner box.

LOT number on the labels at the inner box has to be equal to the LOT numbers on all the products in the inner box.

Use protection plastic with air cushions.

Close the box with 3 adequately placed dots of glue.

The secondary packaging has to protect the products against transport damaging according to standard ISTA 2A. Please see enclosed photos.

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Gyldig fra/valid from: 2011-04-12				Side/page 3 af/of 5	

One "Instruction for use" sheet may be enclosed in each inner box.

One certificate may be enclosed in each inner box.

Without our approval, the inner box, "instruction for use" sheet and the certificate cannot be changed.

5.4 Secondary packaging – outer box:

36 plates in each secondary case – outer box.

LOT number on the labels at the outer box has to be equal to the LOT number on each inner box inside the outer box.

The secondary packaging has to protect the products against transport damaging according to standard ISTA 2A. Please see enclosed photo.

6 Delivery:

Thermo Fisher Scientific's shipping agent will be responsible for packaging on pallets and the shipping.

Cell Seed will get arrival information from the agent.

Pallets:

The 6 inner boxes with products in the outer box delivered on Euro pallets 800 x 1200 mm in a pattern, where there is no total oversize more than 50 mm. regarding width and length. Height is maximal 1600 mm inclusive the pallet.

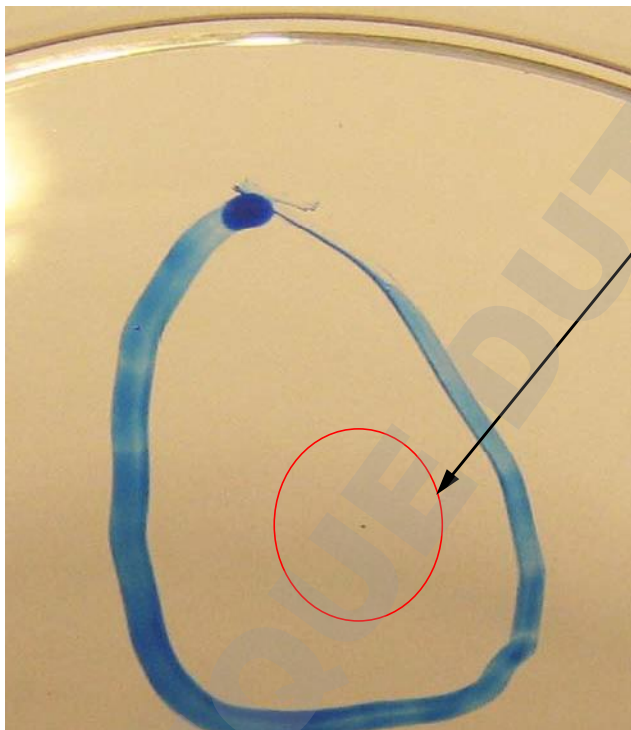
The pallets must be wrapped and closed in a way that secure the products against any damaging. See also point 4.

Godkendt af: Approved by:	rosber	Dato: Date:	2011-03-17	Revisionsnr.: Revision No.:	14-b
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Gyldig fra/valid from: 2011-04-12				Side/page 4 af/of 5	

Photo illustrations:

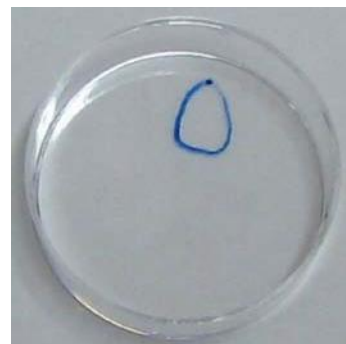
3 Acceptable product:

Generally, black spots must not be visible in a distance of approx. 50 cm in normal reading light (white light). This corresponds to a black spot of 0.2 mm dia. or 0.03 mm² (cf. a TAPPI card = dirt estimation card) inside the bottom of the wells area, which will be used for microscopy.



Black spot.

The photo is enlarged several times. The spot is accurately visible when you look at it in sharp light according to the above text. Not dimensional stable illustration.

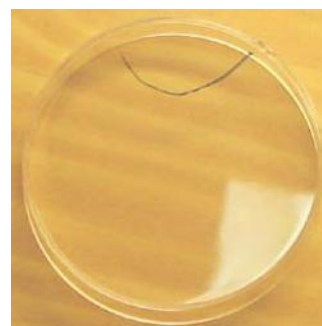


Ø6 cm dish



Scratches.

The photo is enlarged several times. The scratch is placed outside on the bottom and therefore acceptable. Not dimensional stable illustration.

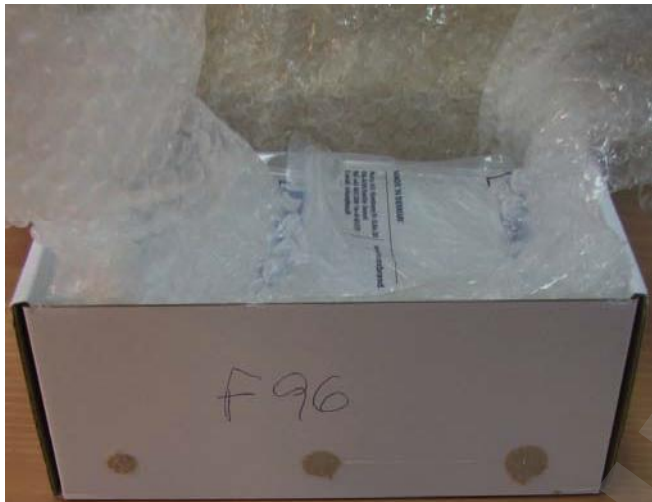


Ø6 cm dish

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Gyldig fra/valid from: 2011-04-12				Side/page 5 af/of 5	

Photo - illustrations:

5 Secondary packaging – inner box:



Top



Front



Photo - illustrations:

5 Secondary packaging – outer box:

