thermoscientific

Instructions for Use Nunc™ IVF 4-Well Dishes

These instructions are valid for:

REF	Description	GTIN
144444	Nunc™ IVF Multidish 4-Well, Nunclon	15713311000127
179830	Nunc™ IVF Multidish 4-Well, Nontreated	15713311000165

Intended Use

Intended purpose/use	The Nunc™ IVF 4-Well Dishes are intended to hold oocytes/embryos during thawing and culturing procedures for in-vitro fertilization (IVF) treatment.
Indications for use	Any of the following: tubal disease, endometriosis, ovulatory dysfunction, or unexplained infertility.
Intended user group	Healthcare professionals.
Use environment	Hospitals, IVF clinics and laboratories.
Intended patient population	Females suited for *in vitro* fertilization.
Contraindications	No known contraindications have been identified. However, IVF should not be performed in women who have a significant risk of morbidity and mortality of pregnancy if IVF were successful.

Instructions for Use

The specific use of these dishes must be defined and implemented by the standard operating procedures and policies of the IVF facility to whom they are sold.

Should not be used continuously for more than 30 days.

Conditions of use

Nunc™ IVF 4-Well Dishes	
Transportation conditions	Ambient temperature (-40°C to 50°C or -40°F to 122°F)
Storage conditions	Room temperature (20°C to 26°C or 68°F to 77°F)

Limitation of use

The Nunc™ IVF 4-Well Dishes are only intended for holding of oocytes/embryos during thawing and culturing procedures for in-vitro fertilization (IVF) treatment.

Technical information

Disposal of the device must be handled according to local regulations.

This medical device complies with Medical Device Regulation (EU) 2017/745 Article 120.

Declaration of Conformity is available from the manufacturer.

⚠ Warnings and precautions

To ensure correct usage, familiarise yourself with the following warnings before using the device.

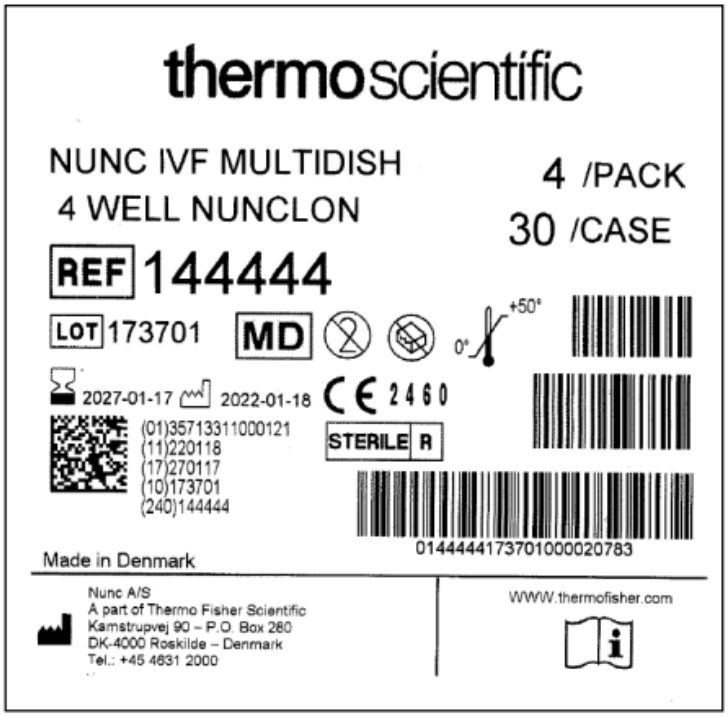
1. Disinfectants, such as alcohol, are known to reduce readability of the package printing. Consequently, we recommend assessing the suitability of your disinfecting solution, or documenting important product traceability information contained on the packaging prior to disinfection.
2. Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
3. Do not use the product if the product packaging is unsealed or damaged.
4. For single use only.
5. Do not use after expiry date.
6. Do not use Hydrogen Peroxide with this product.

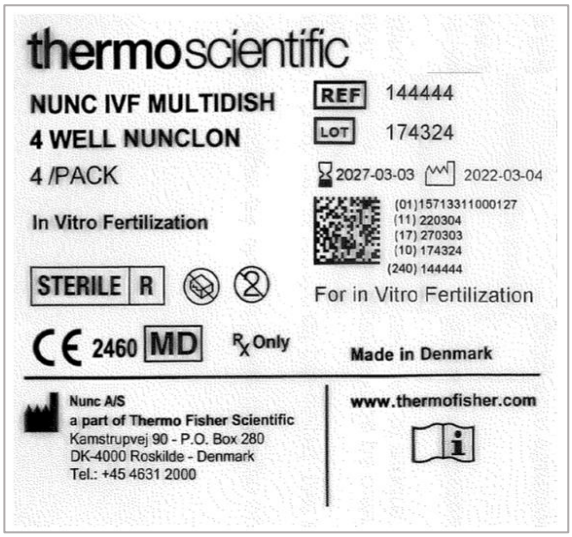
Consult the manufacturer if you experience unexpected operations or serious incidents with the device during or because of its use. The manufacturer will support and if relevant report it to the national authorities.

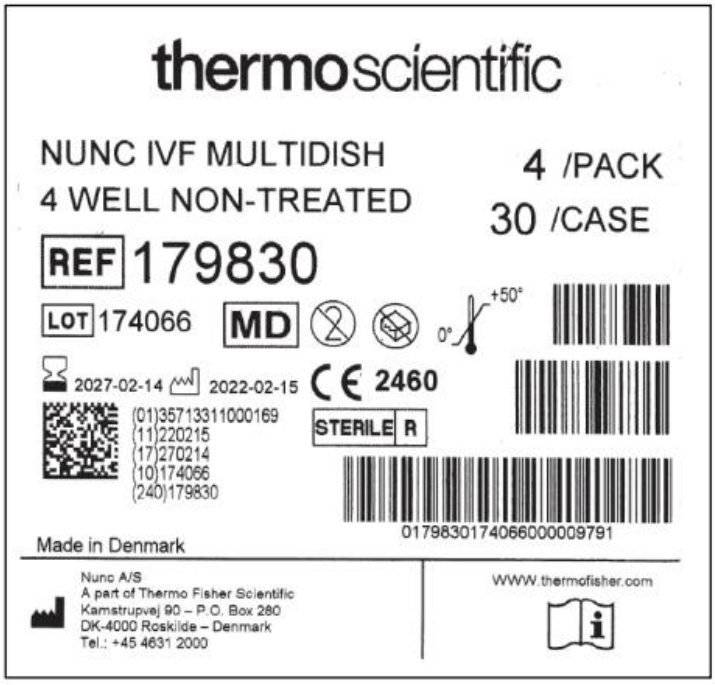
Quality Control Specifications

TEST	RELEASE LIMIT(S)
Pyrogen (endotoxin)	< 0.5 EU/mL
Irradiation Cert. Review	18.0 – 30.0 kGy
Mouse Embryo Assay	a) ≥ 70% 1-cell control embryos → blastocyst in 96 hours b) ≥ 80% test embryos → 1-cell to 2-cell in 24 hours c) ≥ 80% test embryos → 1-cell to blastocyst in 96 hours **Test frequency: Start, middle and end of each production lot. Criteria must be met for acceptance**.
Human Sperm Survival Assay	a) Control and test sperm initial forward progressive motility > 79% b) Control and test sperm progressive motility at 24hr > 70% **Test frequency: Start, middle and end of each production lot. Criteria must be met for acceptance**.

Labeling


thermoscientific
NUNC IVF MULTIDISH
4 WELL NUNCLON
4 /PACK
30 /CASE
REF 144444
LOT 173701
MD
0°
+50°
2027-01-17
2022-01-18
CE 2460
(01)35713311000121
(11)220118
(17)270117
(10)173701
(240)144444
STERILE R
01444441737010000020783
Made in Denmark
Nunc A/S
A part of Thermo Fisher Scientific
Kamstrupvej 90 – P.O. Box 280
DK-4000 Roskilde – Denmark
Tel.: +45 4631 2000
WWW.thermofisher.com


thermoscientific
NUNC IVF MULTIDISH
4 WELL NUNCLON
4 /PACK
In Vitro Fertilization
REF 144444
LOT 174324
2027-03-03
2022-03-04
(01)15713311000127
(11) 220304
(17) 270303
(10) 174324
(240) 144444
STERILE R
CE 2460 MD
Rx Only
For in Vitro Fertilization
Made in Denmark
Nunc A/S
a part of Thermo Fisher Scientific
Kamstrupvej 90 - P.O. Box 280
DK-4000 Roskilde - Denmark
Tel.: +45 4631 2000
www.thermofisher.com


thermoscientific
NUNC IVF MULTIDISH
4 WELL NON-TREATED
4 /PACK
30 /CASE
REF 179830
LOT 174066
MD
0°
+50°
2027-02-14
2022-02-15
CE 2460
(01)35713311000169
(11)220215
(17)270214
(10)174066
(240)179830
STERILE R
01798301740660000009791
Made in Denmark
Nunc A/S
A part of Thermo Fisher Scientific
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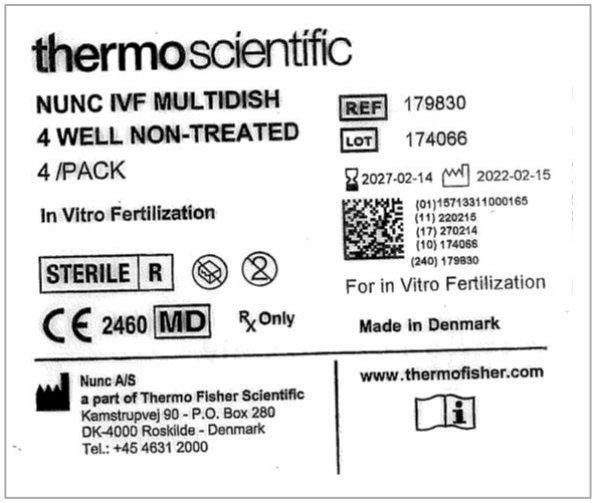
thermoscientific
NUNC IVF MULTIDISH
4 WELL NON-TREATED
4 /PACK
In Vitro Fertilization
REF 179830
LOT 174066
2027-02-14
2022-02-15
(01)15713311000165
(11) 220215
(17) 270214
(10) 174066
(240) 179830
STERILE R
CE 2460 MD
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DK-4000 Roskilde - Denmark
Tel.: +45 4631 2000
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Symbols Glossary in accordance with ISO 15223-1:2021 and other standards

Symbol	Title of Symbol	Description of Symbol	Reference Number
	Manufacturer	Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Date of Manufacture	Indicates the date the medical device was manufactured.	5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	By Prescription Only for US	Indicates that US Federal Law restricts this device to sale by or on the order of a licensed practitioner.	21 CRF 801.15(c)(1)(i)F
	European Conformity Mark	Indicates European technical conformity.	Reg (EU) 2017/745
	*Medical device*	Indicates the item is a *medical device*.	5.7.7