nunc™

"SHIVANI SCIENTIFIC IS NUNC'S EXCLUSIVE REPRESENTATIVE IN INDIA"

All the Nunc IVF products are tested and certified for human use. Each batch is tested for endotoxins and certified non-pyrogenic and mouse embryo tested with 1-cell mouse embryos. The products are CE marked in accordance with the EU medical directions as well as approved by FDA/510k.

IVF Center-Well Dish
with sloped walls & superior thermal stability
'Individually packed in breathable packing'

4-well Dish
'Pack of 4 Dishes'

IVF Snap Cap Tube
with volume graduation
'Beathable packing of 10 Tubes'

IVF Centrifuge Tube
with volume graduation
'Breathable Pack of 5 Tubes'

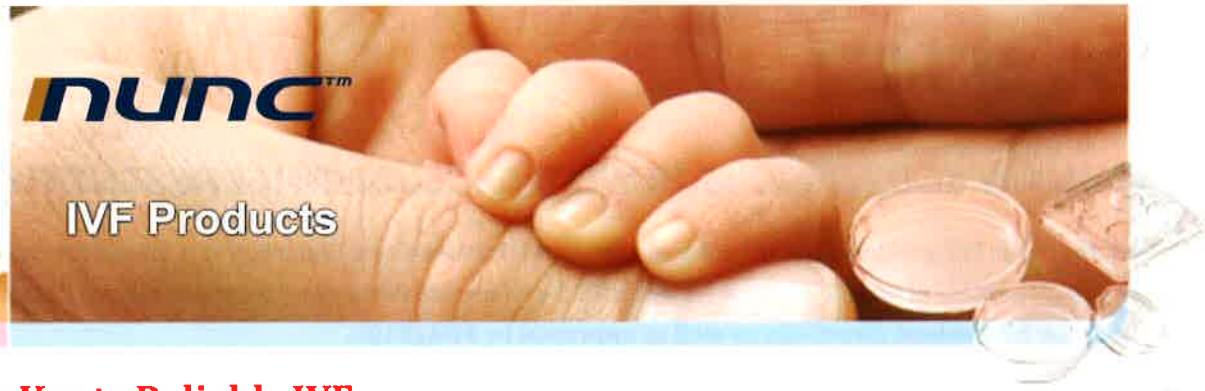
IVF ICSI Dish
with superior thermal stability
'Individually packed in breathable packing'

60, 90 & 35mm IVF Petri Dish
for culture & oocyte pickup
'Pack of 10 Dishes'

Ref	Product	Units per Box	Gamma sterilized	LAL Tested	MEA Tested	CE Marked	FDA/510k*	HSSA	AMES
150268	14ml IVF "Snap Cap" tube	10/500	✓	✓	✓	✓	✓	✓	✓
150255	35mm IVF Petri Dish - Hydrophobic, for microdrop	10/500	✓	✓	✓	✓	✓		✓
150270	60mm IVF Petri Dish - Hydrophobic, for microdrop	10/400	✓	✓	✓	✓	✓		✓
150360	90mm IVF Petri Dish	10/150	✓	✓	✓	✓	✓		✓
150265	IVF Micromanipulation Dish	1/120	✓	✓	✓	✓	✓		✓
150260	IVF Centerwell Dish	1/120	✓	✓	✓	✓	✓		✓
144444	4-Well IVF Dish treated	4/120	✓	✓	✓	✓	✓		✓
137860	11ml IVF Centrifuge tube with CE Mark	5/300	✓	✓	✓	✓	✓	✓	✓
159609	1ml Serological Pipette	1/1000	✓			✓			
159617	5ml Serological Pipette	1/200	✓			✓			
179830	4 Well IVF Dish	4/120	✓	✓	✓	✓	✓		✓

Serological Pipette
1ml & 5ml

Thermo SCIENTIFIC



Quality is the Key to Reliable IVF

Product quality is the single most important criteria when selecting an IVF products partner.

ICMR : THE ASSISTED REPRODUCTIVE TECHNOLOGIES (REGULATION) RULES - 2010

3.20 Quality of consumables used in the laboratory: All disposable plastic ware must be procured from reliable sources after ensuring that they are not toxic to the embryo.

US FDA SUBCHAPTER H--MEDICAL DEVICES SEC. 884.6160 ASSISTED REPRODUCTION LABWARE :

Classification. Class II (special controls) Mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing.

MOUSE EMBRYO ASSAY (MEA) TEST (EMBRYO TOXICITY TEST):

We use the 1-cell stage mouse embryo toxicity test. The standard requirement is for 70% of the fertilized eggs to develop to fully expanded blastocysts in order for product to pass the MEA test. Our requirement is for at least 80% of the fertilized eggs to develop to fully expanded blastocysts to pass the MEA test.This embryo-toxicity test is a release test and only product that has passed the test will be sold.

HUMAN SPERM MOTILITY BIOASSAY TEST (SPERM SURVIVAL AND MOTILITY TEST) :

To pass the HSSA test, the motility of human sperm should be 70% after 24 hours of sample preparation. The control sample motility must be at least 50% of the initial swim-up motility for the test to be acceptable. The HSSA test is a release test and the product will only be sold if it has passed satisfactorily. Not all competitors' products are tested using the HSSA test.

LAL TEST (FOR BACTERIAL ENDOTOXIN):

LAL is short for Limulus Amoebocyte Lysate and is an aqueous extract of blood cells (amoebocytes) from the horseshoe crab, Limulus Polyphemus. LAL reacts with bacterial endotoxin or lipopolysaccharide, which is a membrane component of gram-negative bacteria. This reaction is the basis of the LAL test.
ISO 11137: ISO 11137-1:2006 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

AMES TEST (FOR MUTAGENICITY) :

The test uses strains of the bacterium Salmonella Typhimurium that carry mutations in genes involved in histidine synthesis, so that they require histidine for growth. The small amount of histidine in the growth medium allows the bacteria to grow for an initial time and have the opportunity to mutate. When the histidine is depleted, only bacteria that have mutated to gain the ability to produce its own histidine will survive. The plate is incubated for 48 hours. The mutagenicity of a substance is proportional to the number of colonies observed.

CE MARK :

We guarantee to you that Nunc IVF products are manufactured to the medical device directive class II

ISO 13485 :

This is the ISO standard used by the medical device and In Vitro diagnostics industry.

USP CLASS VI :

United States Pharmacopeia (USP) sets standards for the quality, purity, strength, and consistency of products critical to the public health. Plastics can be graded Class I to VI (1 to 6). Class VI is thus the highest with most extensive testing also used for plastic for implantable devices.

IVF Consumables Product Division (CPD)

Shivani
Enabling life through technology

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