




CERTIFICADO DE ANÁLISE

| | | | |
|---------------------|------------------------------|-----------------|---|
| Produto | Micropipeta Denudação 275 µm | Código | 50090020 |
| Apresentação | 20 unidades | Lote | Ingámed 21020136 Fornecedor 44210103 |
| Fabricação | 01/2021 | Validade | 01/2024 |

| | |
|--|--|
| Indicação de Uso | Indicado para procedimento de Fertilização in Vitro. Manipulação e denudação de oócitos e embriões humanos. |
| Material | Policarbonato transparente, flexível e reto. |
| Armazenamento | Armazenar em temperatura ambiente, em local livre de umidade e fontes de calor para garantir a integridade do produto. |
| Não utilizar o produto caso a embalagem esteja danificada, aberta ou úmida. | |

| Análises e Ensaios | | Resultado |
|---------------------------|--------------------------------------|------------------|
| Análises Microbiológicas | Endotoxina | Conforme* |
| Análise Biológica | Bioensaio com embriões de camundongo | Conforme* |

*Vide Certificado de Análise do Fornecedor em anexo.



Laís Yamada
Bióloga RT – CRBio 108303/07-D



to order of BRASIL

Certificate of Sterilization

relating the products manufactured by us and sold mentioned in
INVOICE No. 402111278 dated January 27th, 2021

REF 447200/20
REF 447135/20
REF 447275/20

LOT 44210103
LOT 44210103
LOT 44210103

All raw materials were adapted optimally to the validated sterilization by gamma irradiation during the developmental phase.

We guarantee the sterility of our products according to DIN EN 11137

Rheinbach/Germany
January 27th, 2021

Reproline medical GmbH

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Ludger Hoppe

- managing director -

CERTIFICATE OF ANALYSIS

ASSAY: MEA – Standard Mouse embryo assay
DESCRIPTION OF TEST PRODUCT: Soft Denudation Tip
REF: 447XXX/20
LOT – NUMBER: 44210103
EXPIRE DATE: 01-2024

PROTOCOL

Three samples were incubated at 37°C for 10 min with previously tested culture medium. Culture dishes were prepared with the extracted medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background, washed thoroughly and cultured in the extracted medium up to Day 5. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using tested medium not exposed to test samples. Embryo development of test and control group was followed every 24 h and photos were taken and included in this report.

CONTROL AND TEST ASSAY RESULTS

Embryo developmental rates of control and tested group

| | n | Day 2 Two-cell stage n(%) | Day 5 blastocyst stage n(%) | Good Quality (morph) Blastocysts n (%) | Result |
|--|----|---------------------------------|-----------------------------------|--|----------------|
| Control | 15 | 15(100) | 14(93,33) | 4(100) | passed* |
| Soft Denudation Tip (LOT: 44210103) | 21 | 21(100) | 21 (100) | 15 (71,43) | passed* |

SUMMARY OF OBSERVATIONS:

All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. The acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

** The endotoxin concentration amounted to < 0.1250 IU/ml and < 1.2500 IU / sample