



# CERTIFICADO DE ANÁLISE

PRODUTOS MÉDICO-HOSPITALARES

|               |                                             |               |            |
|---------------|---------------------------------------------|---------------|------------|
| PRODUTO:      | MICROPIPETA DENUDACAO INGAMED 200UM CX 20UN | INSPEÇÃO:     | 008120     |
| APRESENTAÇÃO: | CAIXA COM 20 UNIDADES                       | LOTE:         | 25040259   |
| DT. PRODUÇÃO: | 31/03/2025                                  | DT. VALIDADE: | 29/02/2028 |

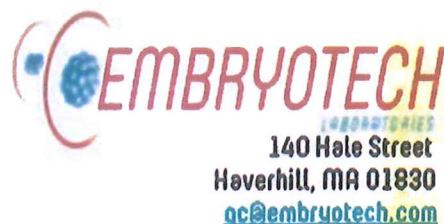
|                         |                                                                                           |
|-------------------------|-------------------------------------------------------------------------------------------|
| USO INDICADO            | Indicada para a manipulação de oócitos e embriões.                                        |
| APLICAÇÃO               | Usada na manipulação de oócitos e embriões, evitando arranhões na superfície ou rupturas. |
| ARMAZENAMENTO           | Armazenar em temperatura ambiente, protegido do calor e umidade.                          |
| MATERIA PRIMA E INSUMOS | Policarbonato                                                                             |

| ANÁLISES E RESULTADOS |                                       | ESPECIFICAÇÃO                         | RESULTADO |
|-----------------------|---------------------------------------|---------------------------------------|-----------|
| BIOMEA                | BIOENSAIO COM EMBRIÕES DE CAMUNDONGOS | Taxa de blastocistos $\geq 80\%$      | 81%       |
| ESTERIL RG            | ESTERILIDADE                          | AUSÊNCIA DE MICRO ORGANISMOS VIÁVEIS  | CONFORME  |
| DIRETIVA EEC 93/42    | DIRETIVA EEC 93/42                    | CONFORMIDADE COM A DIRETIVA EEC/93/42 | CONFORME  |

|                          |         |
|--------------------------|---------|
| RESPONSÁVEL ANÁLISE:     | MELISSA |
| RESPONSÁVEL CONFERÊNCIA: | LUISMAR |



Reproline medical GmbH  
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Germany



ELI Accession Number: REP-5687-0325

Date of completion: 2025-03-25

Lot number: 442501/10/02

Reference number: 447200/20

Description of test article(s): Soft Denudation Tip - 200µm

Assay system requested by customer: 1 mL of culture medium was placed in a tube with the test articles (3) for 30-minutes at 37°C and 5% CO<sub>2</sub>. Post incubation three 12.5µl drops of the culture medium was extracted from the test article tube and placed in the corresponding wells of a culture dish; 7 one-cell mouse embryos were added to each of the three wells and cultured for 96-hours.

Control assay method and results: 21 one-cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium:

|    |   |    |       |                                            |
|----|---|----|-------|--------------------------------------------|
| 21 | / | 21 | 100 % | 1-cell to 2-cell within 24 hr              |
| 21 | / | 21 | 100 % | 1-cell to expanded blastocyst within 96 hr |

For a valid assay, *Embryotech*<sup>™</sup> requires at least 80% of one-cell stage control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 one-cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium that was extracted from the test article tube:

|    |   |    |       |                                            |
|----|---|----|-------|--------------------------------------------|
| 21 | / | 21 | 100 % | 1-cell to 2-cell within 24 hr              |
| 17 | / | 21 | 81 %  | 1-cell to expanded blastocyst within 96 hr |

Pass/Fail = Pass

Summary of observations: All test and control embryos were selected randomly from a common pool of freshly collected embryos and were cultured in the same incubator at 37°C and 5.0% CO<sub>2</sub>. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 81 percent of the test embryos cultured in the extracted culture medium developed to the expanded blastocyst stage within 96-hours.

Signature  
Study Director

2025/03/26  
Date

Signature  
Quality Reviewer

2025/03/27  
Date



to order of BRAZIL

## Certificate of Sterilization

relating the product manufactured by us and sold mentioned in  
INVOICE No. 402514249 dated April 3<sup>rd</sup>, 2025

REF 447200/20 Soft Denudation Tip 200 µm LOT 442501/10/02 MFD 03/2025 Exp. 02/2028

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

**Reproline medical GmbH**

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Rheinbach/Germany  
April 3<sup>rd</sup>, 2025

Ludger Hoppe



## DECLARATION OF CONFORMITY

We  
**Reproline medical GmbH**  
**Zeissstrasse 15**  
**53359 Rheinbach**  
**Germany**

hereby declare that products stated below

REF 447200/20   Soft Denudation Tip 200 µm   LOT 442501/10/02   MFD 03/2025   Exp. 02/2028

### Classification IIa

in compliance with annex V and Annex VII

meet the provision of the  
medical Device Directive 93/42/EEC dated June 14<sup>th</sup>, 1993

The Validity of this declaration is limited to 2 Years after signing

#### Reproline medical GmbH

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April 3<sup>rd</sup>, 2025

Ludger Hoppe