# CERTIFICADO DE ANÁLISE

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|---|---|---|---|
| **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 ≥ 80% | 81% |
| ESTERIL RG | ESTERILIDADE | AUSÊNCIA DE MICRO ORGANIMOS VIÁVEIS | CONFORME |
| DIRETIVA EEC 93/42 | DIRETIVA EEC 93/42 | CONFORMIDADE COM A DIRETIVA EEC/93/42 | CONFORME |

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

# CERTIFICATE OF ANALYSIS

**Reproline medical GmbH**
**Zeissstr. 15**
**53359 Rheinbach**
**Germany**

EMBRYOTECH LABORATORIES
140 Hale Street
Haverhill, MA 01830
qc@embryotech.com

**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% $CO_2$. 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 ($B_6C_3F_1$ X $B_6D_2F_1$) 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™ 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 ($B_6C_3F_1$ X $B_6D_2F_1$) 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% $CO_2$. 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

REPROLINE medical

25 YEARS ANNIVERSARY

to order of BRAZIL

# Certificate of Sterilization

relating the product manufactured by us and sold mentioned in
INVOICE No. 402514249 dated April 3rd, 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

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Rheinbach/Germany
April 3rd, 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 14th, 1993

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

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Rheinbach/Germany

April 3rd, 2025

Ludger Hoppe