



# CERTIFICADO DE ANÁLISE

<b>PRODUTO:</b>	MICROPIPETA DENUDACAO INGAMED 300UM CX 20UN	<b>INSPEÇÃO:</b>	006913
<b>APRESENTAÇÃO:</b>	CAIXA COM 20 UNIDADES	<b>LOTE:</b>	24050331
<b>DT. PRODUÇÃO:</b>	31/03/2024	<b>DT. VALIDADE:</b>	28/02/2027

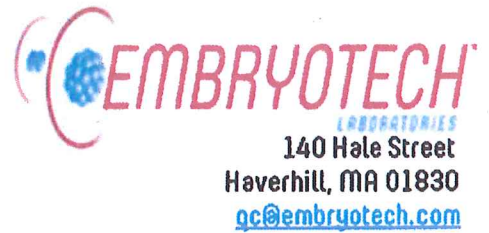
<b>USO INDICADO</b>	Indicada para a manipulação de oócitos e embriões.
<b>APLICAÇÃO</b>	Usada na manipulação de oócitos e embriões, evitando arranhões na superfície ou rupturas.
<b>ARMAZENAMENTO</b>	Armazenar em temperatura ambiente, protegido do calor e umidade.
<b>MATERIA PRIMA E INSUMOS</b>	Policarbonato

ANÁLISES E RESULTADOS		ESPECIFICAÇÃO	RESULTADO
BIOMEA	BIOENSAIO COM EMBRIÕES DE CAMUNDONGO	TAXA DE BLASTOCISTOS = 80%	100%
ESTERIL RG	ESTERILIDADE	AUSÊNCIA DE MICROORGANISMOS VIÁVEIS	CONFORME
DIRETIVA EEC 93/42	DIRETIVA EEC 93/42	CONFORMIDADE COM A DIRETIVA EEC/93/42	CONFORME

<b>RESPONSÁVEL ANÁLISE:</b>	ELIZIA
<b>RESPONSÁVEL CONFERÊNCIA:</b>	ELIZIA



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 53359 Rheinbach  
 Germany



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ELI Accession Number: REP-4094-0424

Date of completion: 04-30-2024

Lot number: 442401/11/04

Reference number: 447300/20

Description of test article(s): Soft Denudation Tip - 300µm

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:

20 / 21 ( 95 %)	1-cell to 2-cell within 24 hr
19 / 21 ( 90 %)	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 (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium that was extracted from the test article tube:

20 / 21 ( 95 %)	1-cell to 2-cell within 24 hr
21 / 21 (100 %)	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>. 90 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the test embryos cultured in the extracted culture medium developed to the expanded blastocyst stage within 96-hours.

*Emm Luzzo*

Signature  
 Study Director

4/30/24

Date

*Adl Gies*

Signature  
 Quality Reviewer

4/30/24

Date

to order of BRAZIL

## Certificate of Sterilization

relating the products manufactured by us and sold mentioned in  
INVOICE No. 402413720 dated May 06<sup>th</sup>, 2024

REF 447135/20	Soft Denudation Tip 135 µm	LOT 442401/03/03	MFD 01/2024	Exp. 12/2026
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442401/11/03	MFD 03/2024	Exp. 02/2027
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442401/02/03	MFD 01/2024	Exp. 12/2026
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442402/14/01	MFD 04/2024	Exp. 03/2027
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442401/12/01	MFD 03/2024	Exp. 02/2027
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442401/13/03	MFD 03/2024	Exp. 02/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/11/01	MFD 03/2024	Exp. 02/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/12/02	MFD 03/2024	Exp. 02/2027
REF 447300/20	Soft Denudation Tip 300 µm	LOT 442401/11/04	MFD 03/2024	Exp. 02/2027

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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Ludger Hoppe

Rheinbach/Germany  
May 06<sup>th</sup>, 2024

## DECLARATION OF CONFORMITY

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

hereby declare that products stated below

REF 447135/20	Soft Denudation Tip 135 µm	LOT 442401/03/03	MFD 01/2024	Exp. 12/2026
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442401/11/03	MFD 03/2024	Exp. 02/2027
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442401/02/03	MFD 01/2024	Exp. 12/2026
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442402/14/01	MFD 04/2024	Exp. 03/2027
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442401/12/01	MFD 03/2024	Exp. 02/2027
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442401/13/03	MFD 03/2024	Exp. 02/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/11/01	MFD 03/2024	Exp. 02/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/12/02	MFD 03/2024	Exp. 02/2027
REF 447300/20	Soft Denudation Tip 300 µm	LOT 442401/11/04	MFD 03/2024	Exp. 02/2027

### 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

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