



# CERTIFICADO DE ANÁLISE

MATERIAIS MÉDICOS HOSPITALARES

<b>PRODUTO:</b>	MICROPIPETA DENUDACAO INGAMED 135UM CX 20UN	<b>INSPEÇÃO:</b>	007235
<b>APRESENTAÇÃO:</b>	CAIXA COM 20 UNIDADES	<b>LOTE:</b>	24080502
<b>DT. PRODUÇÃO:</b>	30/06/2024	<b>DT. VALIDADE:</b>	31/05/2027

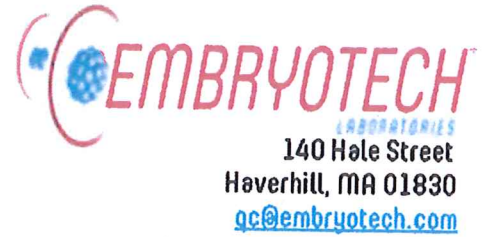
<b>USO INDICADO</b>	Indicada para a manipulação de oócitos e embriões.
<b>APLICAÇÃO</b>	Usada na manipulação de oócitos e embriões, evitando arranhões na superfície ou rupturas.
<b>ARMAZENAMENTO</b>	Armazenar em temperatura ambiente, protegido do calor e umidade.
<b>MATERIA PRIMA E INSUMOS</b>	Policarbonato

ANÁLISES E RESULTADOS		ESPECIFICAÇÃO	RESULTADO
BIOMEA	BIOENSAIO COM EMBRIÕES DE CAMUNDONGOS	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>	LUISMAR



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 Zeissstr. 15  
 53359 Rheinbach  
 Germany



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[qc@embryotech.com](mailto:qc@embryotech.com)

ELI Accession Number: REP-4623-0724

Date of completion: 07-21-2024

Lot number: 442402/26/01

Reference number: 447135/20

Description of test article(s): Soft Denudation Tip - 135µm

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
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>. 100 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.

  
 Signature  
 Study Director

07-22-2024  
 Date

  
 Signature  
 Quality Reviewer

7/23/24  
 Date

to order of BRAZIL

## Certificate of Sterilization

relating the products manufactured by us and sold mentioned in  
INVOICE No. 402413871 dated July 24<sup>th</sup>, 2024

REF 447135/20	Soft Denudation Tip 135 µm	LOT 442402/23/01	MFD 06/2024	Exp. 05/2027
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442402/26/01	MFD 06/2024	Exp. 05/2027
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442402/23/02	MFD 06/2024	Exp. 05/2027
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442402/17/02	MFD 04/2024	Exp. 03/2027
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442402/20/02	MFD 05/2024	Exp. 04/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442402/18/02	MFD 05/2024	Exp. 04/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442402/23/03	MFD 06/2024	Exp. 05/2027
REF 447300/20	Soft Denudation Tip 300 µm	LOT 442402/21/03	MFD 05/2024	Exp. 04/2027

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  
July 24<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 442402/23/01	MFD 06/2024	Exp. 05/2027
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442402/26/01	MFD 06/2024	Exp. 05/2027
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442402/23/02	MFD 06/2024	Exp. 05/2027
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442402/17/02	MFD 04/2024	Exp. 03/2027
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442402/20/02	MFD 05/2024	Exp. 04/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442402/18/02	MFD 05/2024	Exp. 04/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442402/23/03	MFD 06/2024	Exp. 05/2027
REF 447300/20	Soft Denudation Tip 300 µm	LOT 442402/21/03	MFD 05/2024	Exp. 04/2027

### 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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