



# CERTIFICADO DE ANÁLISE

<b>PRODUTO:</b>	MICROPIPETA DENUDACAO INGAMED 135UM CX 20UN	<b>INSPEÇÃO:</b>	006638
<b>APRESENTAÇÃO:</b>	CAIXA COM 20 UNIDADES	<b>LOTE:</b>	24030164
<b>DT. PRODUÇÃO:</b>	01/12/2023	<b>DT. VALIDADE:</b>	01/11/2026

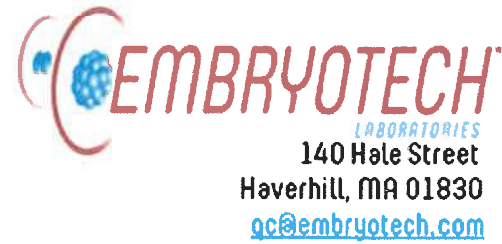
<b>USO INDICADO</b>	Indicada para a manipulação de oócitos e embriões.
<b>APLICAÇÃO</b>	Usada na manipulação de oócitos e embriões, evitando arranhões na superfície ou rupturas.
<b>ARMAZENAMENTO</b>	Armazenar em temperatura ambiente, protegido do calor e umidade.
<b>MATERIA PRIMA E INSUMOS</b>	Polycarbonato

ANÁLISES E RESULTADOS		ESPECIFICAÇÃO	RESULTADO
BIOMEA	BIOENSAIO COM EMBRIÕES DE CAMUNDONGO	TAXA DE SOBREVIVÊNCIA > 80%	100%
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

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



Reproline medical GmbH  
 Zeissstr. 15  
 53359 Rheinbach  
 Germany



140 Hale Street  
 Haverhill, MA 01830  
[qc@embryotech.com](mailto:qc@embryotech.com)

ELI Accession Number: REP-3521-0124

Date of completion: 01-29-2024

Lot number: 442304/49/01

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
20 / 21 ( 95 %)	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:

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>. 95 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

1/29/2024  
 Date

  
 Signature  
 Quality Reviewer

1/29/24  
 Date

to order of BRAZIL

## Certificate of Sterilization

relating the products manufactured by us and sold mentioned in  
INVOICE No. 402413601... dated February 13<sup>th</sup>, 2024

REF 447135/20	Soft Denudation Tip 135 µm	LOT 442304/49/01	MFD 12/2023	Exp. 11/2026
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442304/51/02	MFD 12/2023	Exp. 11/2026
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442303/37/01	MFD 09/2023	Exp. 08/2026
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442304/49/02	MFD 12/2023	Exp. 11/2026
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442304/44/04	MFD 11/2023	Exp. 10/2026
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442304/48/01	MFD 11/2023	Exp. 10/2026
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442304/51/01	MFD 12/2023	Exp. 11/2026
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442304/48/02	MFD 11/2023	Exp. 10/2026
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/01/01	MFD 01/2024	Exp. 12/2026
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/02/02	MFD 01/2024	Exp. 12/2026
REF 447300/20	Soft Denudation Tip 300 µm	LOT 442304/47/02	MFD 11/2023	Exp. 10/2026

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

Zeissstr. 15

53359 Rheinbach

Germany

phone: +49(0)2226/90050

fax: +49(0)2226/900555

Ludger Hoppe

Rheinbach/Germany  
February 13<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 442304/49/01	MFD 12/2023	Exp. 11/2026
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442304/51/02	MFD 12/2023	Exp. 11/2026
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442303/37/01	MFD 09/2023	Exp. 08/2026
REF 447150/20	Soft Denudation Tip 150 µm	LOT 442304/49/02	MFD 12/2023	Exp. 11/2026
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442304/44/04	MFD 11/2023	Exp. 10/2026
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442304/48/01	MFD 11/2023	Exp. 10/2026
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442304/51/01	MFD 12/2023	Exp. 11/2026
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442304/48/02	MFD 11/2023	Exp. 10/2026
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/01/01	MFD 01/2024	Exp. 12/2026
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442401/02/02	MFD 01/2024	Exp. 12/2026
REF 447300/20	Soft Denudation Tip 300 µm	LOT 442304/47/02	MFD 11/2023	Exp. 10/2026

### 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

Rheinbach/Germany  
 Febraury 13<sup>th</sup>, 2024

**Reproline medical GmbH**  
 Zeissstr. 15  
 53359 Rheinbach  
 Germany  
 phone: +49/(0)2226/90050  
 fax: +49/(0)2226/900555  
 Ludger Hoppe