



MATERIAIS MÉDICOS HOSPITALARES

## CERTIFICADO DE ANÁLISE

<b>PRODUTO:</b>	MICROPIPETA DENUDACAO INGAMED 275UM CX 20UN	<b>INSPEÇÃO:</b>	007699
<b>APRESENTAÇÃO:</b>	CAIXA COM 20 UNIDADES	<b>LOTE:</b>	24120782
<b>DT. PRODUÇÃO:</b>	31/10/2024	<b>DT. VALIDADE:</b>	30/09/2027

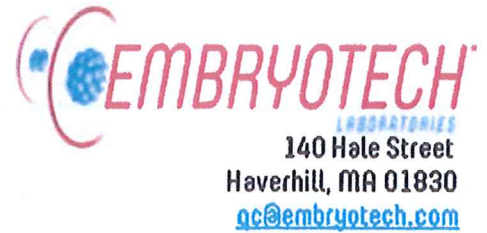
<b>USO INDICADO</b>	Indicada para a manipulação de oócitos e embriões.
<b>APLICAÇÃO</b>	Usada na manipulação de oócitos e embriões, evitando arranhões na superfície ou rupturas.
<b>ARMAZENAMENTO</b>	Armazenar em temperatura ambiente, protegido do calor e umidade.
<b>MATERIA PRIMA E INSUMOS</b>	Policarbonato

ANÁLISES E RESULTADOS		ESPECIFICAÇÃO	RESULTADO
BIOMEA	BIOENSAIO COM EMBRIÕES DE CAMUNDONGOS	TAXA DE BLASTOCISTOS = 80%	95%
ESTERIL R/G	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>	MELISSA
<b>RESPONSÁVEL CONFERÊNCIA:</b>	MELISSA



Reproline medical GmbH  
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 53359 Rheinbach  
 Germany



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ELI Accession Number: REP-5205(R1)-1124

Date of completion: 11-16-2024

Lot number: 442404/41/02

Reference number: 447275/20

**Description of test article(s): Soft Denudation Tip - 275µm**

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
20 / 21 ( 95 %)	1-cell to expanded blastocyst within 96 hr

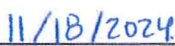
Pass/Fail = Pass

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. 95 percent of the test embryos cultured in the extracted culture medium developed to the expanded blastocyst stage within 96-hours.

  
 \_\_\_\_\_  
 Signature  
 Study Director

  
 \_\_\_\_\_  
 Date

  
 \_\_\_\_\_  
 Signature  
 Quality Reviewer

  
 \_\_\_\_\_  
 Date



to order of BRAZIL

## Certificate of Sterilization

relating the products manufactured by us and sold mentioned in  
INVOICE No. 402414056 dated November 19<sup>th</sup>, 2024

REF 447135/20	Soft Denudation Tip 135 µm	LOT 442404/41/01	MFD 10/2024	Exp. 09/2027
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442403/36/02	MFD 09/2024	Exp. 08/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442403/39/03	MFD 09/2024	Exp. 08/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442404/41/02	MFD 10/2024	Exp. 09/2027

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

CÓPIA CONFIDENCIAL

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Ludger Hoppe

Rheinbach/Germany  
November 19<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 442404/41/01	MFD 10/2024	Exp. 09/2027
REF 447175/20	Soft Denudation Tip 175 µm	LOT 442403/36/02	MFD 09/2024	Exp. 08/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442403/39/03	MFD 09/2024	Exp. 08/2027
REF 447275/20	Soft Denudation Tip 275 µm	LOT 442404/41/02	MFD 10/2024	Exp. 09/2027

### 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

Rheinbach/Germany

November 19<sup>th</sup>, 2024

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