



CERTIFICADO DE ANÁLISE

MATERIAIS MÉDICOS HOSPITALARES

PRODUTO:	MICROPIPETA DENUDACAO INGAMED 275UM CX 20UN	INSPEÇÃO:	007236
APRESENTAÇÃO:	CAIXA COM 20 UNIDADES	LOTE:	24080500
DT. PRODUÇÃO:	31/05/2024	DT. VALIDADE:	30/04/2027

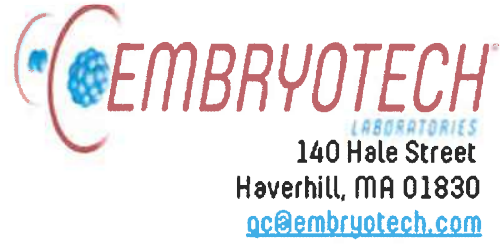
USO INDICADO	Indicada para a manipulação de oócitos e embriões.
APLICAÇÃO	Usada na manipulação de oócitos e embriões, evitando arranhões na superfície ou rupturas.
ARMAZENAMENTO	Armazenar em temperatura ambiente, protegido do calor e umidade.
MATERIA PRIMA E INSUMOS	Policarbonato

ANÁLISES E RESULTADOS		ESPECIFICAÇÃO	RESULTADO
BIOMEA	BIOENSAIO COM EMBRIÕES DE CAMUNDONGOS	TAXA DE BLASTOCISTOS \geq 80%	95%
ESTERIL RG	ESTERILIDADE	AUSÊNCIA DE MICROORGANISMOS VIÁVEIS	CONFORME
DIRETIVA EEC 93/42	DIRETIVA EEC 93/42	CONFORMIDADE COM A DIRETIVA EEC/93/42	CONFORME

RESPONSÁVEL ANÁLISE:	ELIZIA
RESPONSÁVEL CONFERÊNCIA:	LUISMAR



Reproline medical GmbH
 Zeissstr. 15
 53359 Rheinbach
 Germany



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 Haverhill, MA 01830
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ELI Accession Number: REP-4438-0624

Date of completion: 06-28-2024

Lot number: 442402/18/02

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% CO₂. 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
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:

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% CO₂. 90 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. 402413871 dated July 24th, 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 24th, 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 14th, 1993

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

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