



CERTIFICADO DE ANÁLISE

PRODUTO:	MICROPIPETA DENUDACAO INGAMED 135UM CX 20UN	INSPEÇÃO:	006924
APRESENTAÇÃO:	CAIXA COM 20 UNIDADES	LOTE:	24050332
DT. PRODUÇÃO:	31/03/2024	DT. VALIDADE:	28/02/2027

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 CAMUNDONGO	TAXA DE BLASTOCISTOS = 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:	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: 442401/11/03

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% 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:

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
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

4/30/24

Date

Signature
 Quality Reviewer

4/30/24

Date

COPY CONFIDENTIAL

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 14th, 1993

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

Reproline medical GmbH

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Ludger Hoppe

Rheinbach/Germany

May 06th, 2024

to order of BRAZIL

Certificate of Sterilization

relating the products manufactured by us and sold mentioned in
INVOICE No. 402413720 dated May 06th, 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

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May 06th, 2024