



CERTIFICADO DE ANÁLISE

INGAMED

MATERIAIS MÉDICOS HOSPITALARES

PRODUTO:	MICROPIPETA DENUDACAO INGAMED 200UM CX 20UN	INSPEÇÃO:	007697
APRESENTAÇÃO:	CAIXA COM 20 UNIDADES	LOTE:	24120783
DT. PRODUÇÃO:	31/10/2024	DT. VALIDADE:	30/09/2027

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 = 80%	86%
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

RESPONSÁVEL ANÁLISE:	MELISSA
RESPONSÁVEL CONFERÊNCIA:	MELISSA



Reproline medical GmbH
 Zeissstr. 15
 53359 Rheinbach
 Germany



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 Haverhill, MA 01830
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ELI Accession Number: REP-5270-1124

Date of completion: 11-23-2024

Lot number: 442404/41/01

Reference number: 447200/20

Description of test article(s): Soft Denudation Tip - 200µm

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
21 / 21 (100 %)	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
18 / 21 (86 %)	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. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 86 percent of the test embryos cultured in the extracted culture medium developed to the expanded blastocyst stage within 96-hours.


 Signature
 Study Director

11/25/2024
 Date


 Signature
 Quality Reviewer

11/25/24
 Date



to order of BRAZIL

Certificate of Sterilization

relating the products manufactured by us and sold mentioned in
INVOICE No. 402414069 dated November 28th, 2024

REF 447135/20	Soft Denudation Tip 135 µm	LOT 442404/42/02	MFD 10/2024	Exp. 09/2027
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442404/42/01	MFD 10/2024	Exp. 09/2027
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442404/41/01	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 28th, 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 442404/42/02	MFD 10/2024	Exp. 09/2027
REF 447135/20	Soft Denudation Tip 135 µm	LOT 442404/42/01	MFD 10/2024	Exp. 09/2027
REF 447200/20	Soft Denudation Tip 200 µm	LOT 442404/41/01	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 14th, 1993

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

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November 28th, 2024

Ludger Hoppe