CERTIFICADO DE ANÁLISE

PRODUTO:	MICROPIPETA DENUDACAO INGAMED 135UM CX 20UN	**INSPEÇÃO:**	007705
APRESENTAÇÃO:	CAIXA COM 20 UNIDADES	**LOTE:**	24120785
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%	95%
ESTERIL RG	ESTERILIDADE	AUSÊNCIA DE MICRO ORGANIMOS VIÁVEIS	CONFORME
DIRETIVA EEC 93/42	DIRETIVA EEC 93/42	CONFORMIDADE COM A DIRETIVA EEC/93/42	CONFORME

RESPONSÁVEL ANÁLISE:	MELISSA
RESPONSÁVEL CONFERÊNCIA:	MELISSA

CERTIFICATE OF ANALYSIS

Reproline medical GmbH
Zeissstr. 15
53359 Rheinbach
Germany

EMBRYOTECH LABORATORIES
140 Hale Street
Haverhill, MA 01830
qc@embryotech.com

ELI Accession Number: REP-5270-1124 **Date of completion:** 11-23-2024

Lot number: 442404/42/02 **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_2. 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 ($B_6C_3F_1$ X $B_6D_2F_1$) 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 ($B_6C_3F_1$ X $B_6D_2F_1$) 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_2. 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

11/25/2024
Date

Signature
Quality Reviewer

11/25/24
Date

The results relate only to the item(s) tested.

REPROLINE medical

25 YEARS ANNIVERSARY

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

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Rheinbach/Germany
November 28th, 2024

Ludger Hoppe

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St.Nr.: 222/5716/1135
USt-ID Nr.:DE 812344275

Sparkasse KölnBonn / Swift-Code COLSDE33XXX
IBAN DE56 3705 0198 0005 4049 26
Raiffeisenbank Voreifel / Swift-Code GENODED1RBC
IBAN DE96 3706 9627 0035 4330 15

Volksbank Bonn Rhein-Sieg / Swift-Code GENODED1BRS
IBAN DE38 3806 0186 0706 9230 12
Kreissparkasse Köln / Swift-Code COKSDE33XXX
IBAN DE38 3705 0299 0045 8438 69

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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Rheinbach/Germany
November 28th, 2024

Ludger Hoppe