CERTIFICADO DE ANÁLISE

PRODUTO:	MICROPIPETA DENUDACAO INGAMED 200UM CX 20UN	**INSPEÇÃO:**	007234
APRESENTAÇÃO:	CAIXA COM 20 UNIDADES	**LOTE:**	24080499
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 = 80%	100%
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:	ELIZIA
RESPONSÁVEL CONFERÊNCI	LUISMAR

QC

Certificate of Analysis

embryotools
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Phone: + 34 934 497 198

REQUESTED BY: Reproline medical GmbH (Zeissstrasse 15, Rheinbach 53359 Germany)

ASSAY REQUESTED BY CUSTOMER: MEA - Standard Mouse embryo assay

OPERATION PROCEDURE: SOP-MEA-14
TYPE OF ASSAY: Indirect
INTERNAL NUMBER: MEA.022.1711.2024
DATE: 08/07/2024 - 12/07/2024

Product information provided by the customer (Embryotools cannot be held responsible for the veracity of this information)
DESCRIPTION OF TEST PRODUCT: SOFT DENUDATION TIP 200 µm
REF: 447200/20
LOT NUMBER: 442402/20/02
EXP. DATE: 2027-04

PROTOCOL:

Three samples were incubated at 37ºC for 30 min with previously tested culture medium. Culture dishes were prepared with the extracted medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background, washed thoroughly and cultured in the extracted medium in drops of 50ul, in groups of 2, up to Day 5. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using tested medium not exposed to test samples. Embryo development of test and control group was followed every 24 h and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

Embryo developmental rates of control and tested group.

	Embryo development rates				
	n	Day 2 Two-cell stage n (%)	Day 5 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	14 (93.33)	11 (78.57)	**Passed***
SOFT DENUDATION TIP 200 µm (Lot:442402/20/02)	21	21 (100)	21 (100)	11 (52.38)	**Passed***

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO2 and %O2. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

These results are representative of the test samples submitted by the customer.

Nuno Costa-Borges, PhD
Scientific Director

Gloria Calderón, PhD
Quality Assurance

REPROLINE medical

25 YEARS ANNIVERSARY

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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Rheinbach/Germany
July 24th, 2024

Ludger Hoppe

REPROLINE medical

25 YEARS ANNIVERSARY

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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Rheinbach/Germany
July 24th, 2024

Ludger Hoppe