



# CERTIFICADO DE ANÁLISE

<b>Produto</b>	Micropipeta Denudação 275 µm	<b>Código</b>	50090020
<b>Apresentação</b>	20 unidades	<b>Lote</b>	Ingámed 21080627 Fornecedor 44210203
<b>Fabricação</b>	04/2021	<b>Validade</b>	04/2024

<b>Indicação de Uso</b>	Indicado para procedimento de Fertilização in Vitro. Manipulação e denudação de oócitos e embriões humanos.
<b>Material</b>	Polycarbonato transparente, flexível e reto.
<b>Armazenamento</b>	Armazenar em temperatura ambiente, em local livre de umidade e fontes de calor para garantir a integridade do produto.
<b>Não utilizar o produto caso a embalagem esteja danificada, aberta ou úmida.</b>	

Análises e Ensaios		Resultado
Análises Microbiológicas	Endotoxina	Conforme*
Análise Biológica	Bioensaio com embriões de camundongo	Conforme*
Esterilização	Esterilização por radiação gama	Conforme*

\*Vide Certificado de Análise do Fornecedor em anexo.

*Lais Yamada*  
**Lais A. Yamada**  
**CRBio 108303/07-D**



## DECLARATION OF CONFORMITY

We  
Reproline medical GmbH  
Zeissstrasse 15  
53359 Rheinbach  
Germany

hereby declare that products stated below

REF 447275/20	Soft Denudation Tip 275 µm	LOT 44210203	Manufactured 04/2021	Expired 04/2024
REF 447175/20	Soft Denudation Tip 175 µm	LOT 44210203	Manufactured 06/2021	Expired 04/2024

### Classification IIa

in compliance with annex V and Annex VII

meet the provision of the  
medical Device Directive 93/42/EEC dated June 14<sup>th</sup>, 1993

The Validity of this declaration is limited to 3 Years after signing

July 30<sup>th</sup>, 2021

Reproline medical GmbH

Zeissstr. 15  
53359 Rheinbach  
Germany

Ludger Hoppe (managing director)

+49(0)2226/9005-55

Reproline medical GmbH  
Zeissstr. 15, 53359 Rheinbach, Germany  
Tel: +49(0)2226-9005-0  
Fax: +49(0)2226-9005-55  
[info@reproline-ivf.de](mailto:info@reproline-ivf.de) / [www.reproline-medical.com](http://www.reproline-medical.com)

Geschäftsführer  
Ludger Hoppe / Thomas Wilutzki  
HRB 10589 / AG Bonn  
St.Nr.: 222/5716/1135  
USt-ID Nr.: DE 812344275

Sparkasse KölnBonn / Swift-Code COLSDE33XXX  
IBAN DE55 3705 0198 0005 4049 26  
Raiffeisenbank Voreifel / Swift-Code GENODE33XXX  
IBAN DE96 3706 9627 0035 4330 15

Volksbank Bonn Rhein-Sieg / Swift-Code GENODE33XXX  
IBAN DE38 3806 0186 0706 9230 12  
Kreissparkasse Köln / Swift-Code COXSDE33XXX  
IBAN DE38 3705 0299 0045 8438 69

## CERTIFICATE OF ANALYSIS

**ASSAY:** MEA – Standard Mouse embryo assay  
**DESCRIPTION OF TEST PRODUCT:** Soft Denudation Tip  
**REF:** 447XXX/20  
**LOT – NUMBER:** 44210203  
**EXPIRE DATE:** 04-2024

### PROTOCOL

Three samples were incubated at 37°C for 10 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 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.

### CONTROL AND TEST ASSAY RESULTS

Embryo developmental rates of control and tested group

	n	Day 2 Two-cell stage n(%)	Day 5 blastocyst stage n(%)	Good Quality (morph) Blastocysts n (%)	Result
Control	15	15(100)	14(93,33)	10(71,43)	passed*
Soft Denudation Tip (LOT: 44210203)	21	21(100)	17 (80,95)	17 (100)	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 %CO<sub>2</sub> and %O<sub>2</sub>. The 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.

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

\*\* The endotoxin concentration amounted to < 0,0150 EU/device



to order of BRAZIL

## Certificate of Sterilization

relating the products manufactured by us and sold mentioned in  
INVOICE No. 402111783 dated July 30<sup>th</sup>, 2021

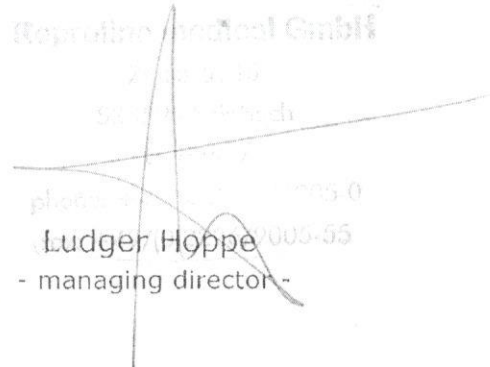
REF 447275/20                      LOT 44210303  
REF 447175/20                      LOT 44210203

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

Rheinbach/Germany  
July 30<sup>th</sup>, 2021

Reproline medical GmbH

  
Ludger Hoppe  
- managing director -

Reproline medical GmbH  
Zeissstr. 15, 53359 Rheinbach, Germany  
Tel.: +49(0)2226-9005-0  
Fax: +49(0)2226-9005-55  
info@reproline-med.de / www.reproline-medical.com

Geschäftsführer  
Ludger Hoppe / Thomas Wölzlitz  
HRB 10589 / AG Bonn  
St.Nr.: 222/5716/1135  
USt-ID Nr.: DE 812344275

Sparkasse KölnBonn / Swift Code COLSDE33XXX  
IBAN DE56 3705 0193 0005 4049 26  
Raiffeisenbank Voreifel / Swift Code GENODE1RBC  
IBAN DE96 3705 9627 0035 4330 15

Volksbank Bonn Rhein-Sieg / Swift Code GENODE1BRS  
IBAN DE38 3806 0186 0706 9230 12  
Kreissparkasse Köln / Swift Code COXSDE33XXX  
IBAN DE38 3705 0299 0045 8438 69