



CERTIFICADO DE ANÁLISE

| | | | |
|---------------------|------------------------------|-----------------|---|
| Produto | Micropipeta Denudação 175 µm | Código | 50090018 |
| Apresentação | 20 unidades | Lote | Ingámed 21080598 Fornecedor 44210203 |
| Fabricação | 06/2021 | Validade | 04/2024 |

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

| 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 A. 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 44210303 | Manufactured 07/2021 | Expired 07/2024 |
| 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 14th, 1993

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

July 30th, 2021

Reproline medical GmbH

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Geschäftsführer
Ludger Hoppe / Thomas Willutzki
HRB 10589 / AG Bonn
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 DE98 3708 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



to order of BRAZIL

Certificate of Sterilization

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

REF 447275/20
REF 447175/20

LOT 44210303
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 30th, 2021

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- managing director -

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