ITALCERT

CERTIFICATO N° 505SGQ07

CERTIFICATE N° 505SGQ07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Moncenisio, 4 – IT 20900 MONZA (MB)

nelle Strutture Operative di cui in allegato 1 al presente Certificato
e per le attività elencate
In the Operative Units as per Annex 1 of this Certificate and for the indicated activities

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1
This Certificate should be made public only in integral form complete Annex 1
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR
Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Modifica *Modified Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2025-01-10	2026-10-29

Settore IAF 14 - 29

Digitally signed by Ceaicovschi Tudor
Date: 2025.06.06 11:51:47 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

Allegato 1 al Certificato n° 505SGQ07

Annex 1 of Certificate 505SGQ07

Indirizzo Sede	Dettaglio attività erogate
Regione Monforte, 30 IT 14053 CANELLI (AT)	Uffici/amministrazione, ufficio tenico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.
Strada Provinciale 592, n°70 Frazione San Vito IT 14042 Calamandrana (AT)	Magazzino prodotti finiti

La validità del presente Allegato è vincolata a quella del Certificato N 505SGQ07

The validity of this Annex is bound to the Certificate N 505SGQ07

2025-01-10

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreements

This is a translation of the certificate ES16/20725.01

DELTALAB, S.L.

Pol.Ind. La Llana, Plaza de la Verneda, 1, 08191 Rubí, Barcelona

Has been assessed under the management system of the certified organisation defined in the main certificate ES16/20725 as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis.
Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products and cosmetics.

This certificate is valid from 11 October 2022 until 11 October 2025 and remains valid subject to satisfactory surveillance audits.

Issue 2.
The validity of this certificate depends on the validity of the main certificate.

SGS International Certification Services Iberica, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España
t +34 91 313 8115 - www.sgs.com

ISO CONSULTING
ИСОКОНСАЛТИНГ

Goodwill Certification System
IST
«InterSertTest»

RA.RU.13HA90

ISO 17021
MANAGEMANT SYSTEMS CERTIFICATION

object of conformity confirmation
ISO 13485:2016

Certification System

Works and Services, Management Systems

InterSertTest

MANAGEMENT SYSTEM CERTIFICATION BODY
OF LIMITED LIABILITY COMPANY
"ISO CONSULTING"

PREMISES 126, 127, 128, AND 129, BLOCK 2, FLOOR 2, 3, DAVYDKOVSKAYA STR., MOSCOW, 121352
UNIQUE NUMBER OF THE ACCREDITATION RECORD IN THE REGISTER OF ACCREDITED PERSONS: RA.RU.13HA90

CERTIFICATE OF CONFORMITY

Issue 2. QMS is certified since January 2021

№ РОСС RU.С.04ША.СК.2015

Is given to: "Research and Production Company "VINAR"
Limited Liability Company
("RPC "VINAR", LLC)

TIN 5023001024

Office VIII, Building 7A, 5, Gospitalniy Val, Moscow, 105094

THIS CERTIFICATE CERTIFIES THAT

QUALITY MANAGEMENT SYSTEM AS APPLIED TO DESIGN, DEVELOPMENT, PRODUCTION AND SALES OF THE FOLLOWING MEDICAL DEVICES: CHEMICAL AND BIOLOGICAL STERILIZATION, DISINFECTION AND DECONTAMINATION INDICATORS; PROCESS CHALLENGE DEVICES; CHEMICAL INDICATORS FOR DISINFECTING AND STERILIZING SOLUTIONS CONCENTRATION CONTROL; WASH MONITORING AND PRE-CLEANING TESTS; PACKAGING MATERIALS FOR STERILIZATION AND WASHING; "COLD CHAIN" CONTROL INDICATORS; DISPOSABLES FOR STERILIZATION AREAS, OPERATING ROOMS AND CLEAN AREAS; ANTISEPTICS AND DISINFECTANTS

COMPLIES WITH THE REQUIREMENTS OF ISO 13485:2016

The Appendix forms are integral part of the Certificate of Conformity

By virtue of: *Decision of the Certification Body № 0096 dated 24 January 2024*

THIS CERTIFICATE SHALL BIND THE ORGANIZATION TO MAINTAIN THE STATE OF THE QUALITY MANAGEMENT SYSTEM IN THE WORKABLE CONDITION IN COMPLIANCE WITH THE REQUIREMENTS OF THE ABOVE STANDARD, TO CONFIRM THIS COMPLIANCE BY RESULTS OF THE ANNUAL INSPECTION CHECK-UP IN "ISO CONSULTING" LLC MANAGEMENT SYSTEM CERTIFICATION BODY WITHIN THE ENTIRE PERIOD OF THE CERTIFICATE DURATION.

Issued 24 January 2024

Expiry date: 24 January 2027
(If the inspection control is passed)

ISO 13485

Terms for the start of the first inspection: Not later than 18 January 2025
Terms for the start of the second inspection: Not later than 18 January 2026

S.A. KORKIN
Head of the Certification Body

T.V. GRICHANAYA
Head of the Audit Team

№ 006416

FEDERAL AGENCY OF TECHNICAL REGULATION AND METROLOGY
Goodwill Certification System "InterSertTest", Registration №РОСС RU.3570.04ША00
Certification parent body "EuroStandard - certifica" OGRN 1097746081498
Address: 121170, Moscow, Kutuzovskiy prospect 36, build. 3, tel: (495) 744-2923

Certification System

Works and Services, Management Systems

InterSertTest

Appendix
Is an integral part of
Certificate № РОСС RU.C.04ША.СК.2015

Scope of Certification of the Quality Management System

Design, development, production and sales of the following medical devices: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; packaging materials for sterilization and washing; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas; antiseptics and disinfectants except p. 7.5.3, p. 7.5.4, p. 7.5.6 in terms of the validation of the application of computer software used in production and service provision, p. 7.5.9.2, p. 7.5.10, 8.2.6 in terms of records, for implantable products, for the identification of personnel conducting any type of control or testing ISO 13485:2016

"Research and Production Company "VINAR"
Limited Liability Company,

Including:

Production site "RPC "VINAR", LLC
17/2 Kolontsova str., Mytishchi, Moscow region, 141009
Production medical devices: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas

Production site "RPC "VINAR", LLC
51b, Bolshaya Protechnaya str., Pereslavl-Zalessky, Yaroslavl region, 152020,
Production medical devices: packaging materials for sterilization and washing; antiseptics and disinfectants

S.A. KORKIN
Head of the Certification Body _____

T.V. GRICHANAYA
Head of the Audit Team _____

FEDERAL AGENCY OF TECHNICAL REGULATION AND METROLOGY
Goodwill Certification System "InterSertTest", Registration №РОСС RU.3570.04ША00
Certification parent body "EuroStandard - certifica" OGRN 1097746081498
Address: 121170, Moscow, Kutuzovskiy prospect 36, build. 3, tel: (495) 744-2923

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Filtered Pipette Tips**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

BOEN HEALTHCARE CO., LTD

CERTIFICATE OF ANALYSIS

Report No.: GM04-BN24

Product Name: Eppendorf Pipette Tips	Lot. No.: 20241220
MFG. Date: 2024-12	EXP. Date: 2029-11
Raw Material: PP	Specification: 200μL
Standard: Enterprise Standard	
Package: 1000pcs/bag, 50000pcs/ctn	
Quantity: 500000pcs	Report Date: 2025.01.10

Test Items	Technical Requirement	Inspection Level	Sample	AQL		Defect Qty	Result
Dimension	L: 45±1mm	5pcs/lot	5pcs	0		0	Pass
				Ac	Re		
				0	1		
Appearance	No burr, black dot, dust, scratch, no oil spot, breakage, shrink color correct, blocking is not permitted	GB/T 2828.1-2003 Normal test level II	800pcs	1.5		0	Pass
				Ac	Re		
				21	22		
Function	Can be assembled with pipettor well	10pcs/lot	10pcs	0		0	Pass
				Ac	Re		
				0	1		
Package	Label and marking should be clear, correct and the label should be on correct loction.	1 outer box/lot	1 outer box	0		0	Pass
				Ac	Re		
				0	1		
Conclusion	The product meets all the requirement by our test.						

Inspected by: Leo Sun

Checked by: Irene Qiao

BOEN HEALTHCARE CO., LTD

CERTIFICATE OF ANALYSIS

Report No.: GM04-BN24

Product Name: Eppendorf Pipette Tips		Lot. No.: 20241220					
MFG. Date: 2024-12		EXP. Date: 2029-11					
Raw Material: PP		Specification: 1000μL					
Standard: Enterprise Standard							
Package: 500pcs/bag, 15000pcs/ctn							
Quantity: 1000000pcs		Report Date: 2025.01.20					
Test Items	Technical Requirement	Inspection Level	Sample	AQL		Defect Qty	Result
Dimension	L: 69±1mm	5pcs/lot	5pcs	0		0	Pass
				Ac	Re		
				0	1		
Appearance	No burr, black dot, dust, scratch, no oil spot, breakage, shrink color correct, blocking is not permitted	GB/T 2828.1-2003 Normal test level II	800pcs	1.5		0	Pass
				Ac	Re		
				21	22		
Function	Can be assembled with pipettor well	10pcs/lot	10pcs	0		0	Pass
				Ac	Re		
				0	1		
Package	Label and marking should be clear, correct and the label should be on correct loction.	1 outer box/lot	1 outer box	0		0	Pass
				Ac	Re		
				0	1		
Conclusion	The product meets all the requirement by our test.						

Inspected by: Leo Sun

Checked by: Irene Qiao

Орган по сертификации систем менеджмента ООО «ЕВРОСЕРТИФИКА»
Уникальный номер записи об аккредитации в реестре аккредитованных лиц
Федеральной службы по аккредитации №RA.RU.13HB10

Сертификат RA.RU.HB10.00031/24

Система Менеджмента

ООО «МиниМед»

Российская Федерация, 241520, Брянская область, Брянский район,
с. Супонево, ул. Шоссейная, д. 17А

Была оценена и сертифицирована, как отвечающая требованиям

ГОСТ ISO 13485-2017

Для следующей области применения

Проектирование, разработка, производство и продажа медицинских изделий: лабораторной посуды, красителей, реагентов, наборов реагентов, принадлежностей и приборов для in-vitro диагностики, а также техническое обслуживание медицинских изделий для in-vitro диагностики.

Более подробная информация относительно области применения настоящего сертификата, а также применимости требований ГОСТ ISO 13485-2017 может быть получена у держателя сертификата

Настоящий сертификат действителен с 13.12.2024 по 12.12.2027
при подтверждении надзорными аудитами.
Подлежит ресертификационному аудиту до 12.12.2027
Выпуск 1. Сертифицировано с 13.12.2024

Уполномоченное лицо
Руководитель Органа по
сертификации систем менеджмента
Андрей Иванов

Орган по сертификации систем менеджмента ООО «ЕВРОСЕРТИФИКА»
Российская Федерация, 117587, г. Москва, Варшавское шоссе, дом 125, строение 1, секция 9
Телефон: +74953693603 Факс: +7 4953693603 www. eurocertifica.ru

00060

АО «ОПЦИОН», Москва, 2023 г., «Т», ТЗ № 579.

ООО «МиниМед»

Российская Федерация, 241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

ГОСТ ISO 13485-2017

Производственные площадки ООО «МиниМед»:

Площадка 1: ООО "МиниМед", Российская Федерация, 241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А
Площадка 2: ООО "МиниМед", Российская Федерация, 241520, Брянская область, Брянский район, с. Супонево, пер. Комсомольский, д. 7, корп. 2а
Площадка 3: Филиал ООО «МиниМед», Российская Федерация, 242600, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 5

00061

АО «ОПЦИОН», Москва, 2023 г., «Г», ТЗ № 579

Second Edition

October 2010

TissueLyser Handbook

For high-throughput disruption of biological samples

QIAGEN®

Sample & Assay Technologies

QIAGEN Sample and Assay Technologies

QIAGEN is the leading provider of innovative sample and assay technologies, enabling the isolation and detection of contents of any biological sample. Our advanced, high-quality products and services ensure success from sample to result.

QIAGEN sets standards in:

- Purification of DNA, RNA, and proteins
- Nucleic acid and protein assays
- microRNA research and RNAi
- Automation of sample and assay technologies

Our mission is to enable you to achieve outstanding success and breakthroughs. For more information, visit www.qiagen.com .

Contents

Product Contents

TissueLyser II*	
Catalog no.	**85300**
TissueLyser II (100–120/220–240 V, 50/60Hz)	1
Operating Instructions	1
Handbook	1

* The TissueLyser II (cat. no. 85300) is an improved version of the TissueLyser (cat. no. 85200, 85210, or 85220; no longer available). All instructions and protocols in this handbook apply to both the TissueLyser II and the TissueLyser.

Storage

The TissueLyser should be stored upright in a dry environment at room temperature (15–25°C).

Product Use Limitations

The TissueLyser is intended for molecular biology applications. This product is not intended for the diagnosis, prevention, or treatment of a disease.

All due care and attention should be exercised in the handling of many of the materials described in this text. We recommend all users of QIAGEN® products to adhere to the NIH guidelines that have been developed for recombinant DNA experiments, or to other applicable guidelines.

Product Warranty and Satisfaction Guarantee

QIAGEN guarantees the performance of all products in the manner described in our product literature. The purchaser must determine the suitability of the product for its particular use. Should any product fail to perform satisfactorily due to any reason other than misuse, QIAGEN will replace it free of charge or refund the purchase price. We reserve the right to change, alter, or modify any product to enhance its performance and design. If a QIAGEN product does not meet your expectations, simply call your local Technical Service Department or distributor. We will credit your account or exchange the product — as you wish. Separate conditions apply to QIAGEN scientific instruments, service products, and to products shipped on dry ice. Please inquire for more information.

A copy of QIAGEN terms and conditions can be obtained on request, and is also provided on the back of our invoices. If you have questions about product specifications or performance, please call QIAGEN Technical Services or your local distributor (see back cover or visit www.qiagen.com).

Technical Assistance

At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Service Departments are staffed by experienced scientists with extensive practical and theoretical expertise in sample and assay technologies and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the TissueLyser or QIAGEN products in general, please do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/Support or call one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit www.qiagen.com).

Safety Information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate material safety data sheets (MSDSs). These are available online in convenient and compact PDF format at www.qiagen.com/Support/MSDS.aspx where you can find, view, and print the MSDS for each QIAGEN kit and kit component.

24-hour emergency information

Emergency medical information in English, French, and German can be obtained 24 hours a day from:

Poison Information Center Mainz, Germany

Tel: +49-6131-19240

Introduction

Principle

The TissueLyser provides rapid and efficient disruption of up to 192 biological samples, including animal and human tissues, plant tissues, bacteria, and yeast. Disruption and homogenization are achieved through the beating and grinding effect of beads on the sample material as they are shaken together in the grinding vessels.

Disruption is critically important in order to release the nucleic acids from the sample material. Homogenization of the material acts to shear the high-molecular-weight cellular proteins and carbohydrates that may otherwise reduce binding of DNA and RNA to silica membranes or magnetic particles. Sample disruption using, for example, a mortar and pestle does not result in efficient homogenization. The TissueLyser both disrupts and homogenizes sample material in one simple and reliable step.

The TissueLyser is easily programmed to provide variable speeds from 3 to 30 Hz (180–1800 oscillations/minute) and run times from 10 seconds to 99 minutes.

Applications

The ability to process up to 192 samples per run makes the TissueLyser the ideal front-end solution to access biological information for genomics, transcriptomics, and proteomics applications. For next-generation high-throughput sequencing technologies such as polony sequencing, the TissueLyser is the disruption instrument of choice.

The TissueLyser enables fast and uniform disruption of animal and human tissues, plant tissues, bacteria, and yeast in various sample volumes in several formats. QIAGEN offers adapter sets for 2 x 96 collection microtubes (1.2 ml) or 2 x 24 microcentrifuge tubes (2 ml) as well as stainless steel and tungsten carbide beads. For disruption of large samples, grinding jar sets (10 ml) with stainless steel or Teflon® grinding balls are also available from QIAGEN. For more details about these and other accessories for the TissueLyser, see Appendix A (page 27).

The TissueLyser provides efficient disruption of biological material in each sample vessel for reproducible, high-quality results in downstream applications such as the purification of total DNA or RNA from a variety of human, animal, and plant tissues. A wide range of QIAGEN sample purification kits are compatible with the TissueLyser (see Tables 1–6, pages 7–10). Sample purification can be performed manually or can be automated using the QIAcube® , QIAsymphony™ SP, EZ1® Advanced, or BioRobot® or BioSprint® workstations. For more information about automated solutions from QIAGEN, see Appendix B (page 29).

This handbook provides guidelines on disrupting and homogenizing various sample materials for subsequent purification of DNA or RNA. Specific details on disruption and homogenization and nucleic acid purification, such as the amount of starting material and lysis buffer to use, can be found in the handbook supplied with each QIAGEN sample purification kit.

Table 1. Kits for RNA purification from animal or human tissues using spin columns

Sample type	Kit	Kit format	Page
Easy-to-lyse tissues (e.g., kidney, liver, and lung)	RNeasy® Micro Kit	Up to 5 mg tissue; automatable on QIAcube	16
	RNeasy Mini Kit	Up to 30 mg tissue; automatable on QIAcube	16
	RNeasy Protect Mini Kit	Up to 20 mg RNA*later*® stabilized tissue; automatable on QIAcube	16
	RNeasy Plus Micro Kit	Up to 5 mg tissue; includes gDNA Eliminator spin columns	16
	RNeasy Plus Mini Kit	Up to 30 mg tissue; includes gDNA Eliminator spin columns; automatable on QIAcube	16
Fiber-rich tissues (e.g., heart and muscle)	RNeasy Fibrous Tissue Mini Kit	Up to 30 mg tissue	16
	RNeasy Fibrous Tissue Midi Kit	Up to 250 mg tissue	16
Any type of tissue, including fatty tissues (e.g., adipose tissue and brain)	RNeasy Lipid Tissue Mini Kit	Up to 100 mg tissue; automatable on QIAcube	16
	miRNeasy Mini Kit	Up to 100 mg tissue; automatable on QIAcube	16

Table 2. Kits for RNA purification from animal or human tissues using magnetic particles or 96-well plates

Sample type	Kit	Kit format	Page
Easy-to-lyse tissues (e.g., kidney, liver, and lung)	EZ1 RNA Tissue Mini Kit	Magnetic particles; up to 10 mg tissue; automated on EZ1 Advanced* (1–6 samples per run)	16
	MagAttract® RNA Tissue Mini M48 Kit	Magnetic particles; up to 10 mg tissue; automated on BioRobot M48 (6–48 samples per run)	16
	QIAsymphony RNA Kit	Magnetic particles; up to 50 mg tissue; automated on QIAsymphony SP (1–96 samples per run)	16
Any type of tissue	EZ1 RNA Universal Tissue Kit	Magnetic particles; up to 50 mg tissue; automated on EZ1 Advanced* (1–6 samples per run)	16
	MagAttract RNA Universal Tissue M48 Kit	Magnetic particles; up to 50 mg tissue; automated on BioRobot M48 (6–48 samples per run)	16
	RNeasy 96 Universal Tissue Kits	96-well plate; up to 100 mg tissue; automatable on BioRobot Universal System (up to 80 mg tissue)†	16
	miRNeasy 96 Kit	96-well plate; up to 100 mg tissue	16

* Also automatable on BioRobot EZ1.

† Also automatable on BioRobot Gene Expression — Real-Time RT-PCR and BioRobot 8000.

Table 3. Kits for RNA purification from plant tissues, bacteria, and yeast

Sample type	Kit	Kit format	Page
Plant tissue (e.g., leaf)	RNeasy Plant Mini Kit	Spin column; up to 100 mg tissue; automatable on QIAcube	18
	RNeasy 96 Kit	96-well plate; up to 25 mg tissue	18
Bacteria (Gram-postive and -negative)	RNeasy Protect Bacteria Mini Kit	Spin column; up to 2.5 x 10^8 cells	20
	RNeasy Protect Bacteria Midi Kit	Spin column; up to 1.5 x 10^9 cells	20
Yeast	RNeasy Mini Kit	Spin column; up to 5 x 10^7 cells	21

Table 4. Kits for DNA purification from animal or human tissues

Kit	Kit format	Page
DNeasy® Blood & Tissue Kit	Spin column; up to 25 mg tissue; automatable on QIAcube	22
DNeasy 96 Blood & Tissue Kit	96-well plate; up to 20 mg tissue	22
QIAamp® DNA Mini Kit	Spin column; up to 25 mg tissue; automatable on QIAcube	22
EZ1 DNA Tissue Kit	Magnetic particles; up to 40 mg tissue; automated on EZ1 Advanced* (1–6 samples per run)	22
MagAttract DNA Mini M48 Kit	Magnetic particles; up to 40 mg tissue; automated on BioRobot M48 (6–48 samples per run)	22
QIAsymphony DNA Mini Kit	Magnetic particles; up to 50 mg tissue; automated on QIAsymphony SP (1–96 samples per run)	22

* Also automatable on BioRobot EZ1.

Table 5. Kits for DNA purification from plant tissues

Kit	Kit format	Page
DNeasy Plant Mini Kit	Spin column; up to 100 mg tissue; automatable on QIAcube	23
DNeasy Plant Maxi Kit	Spin column; up to 1 g tissue	25
DNeasy 96 Plant Kit	96-well plate; up to 50 mg tissue	23
MagAttract 96 DNA Plant Core Kit	Magnetic particles; up to 100 mg tissue; automatable on BioRobot Plant Science System — Genotyping*	23
BioSprint 15 DNA Plant Kit	Magnetic particles; up to 50 mg tissue; automated on BioSprint 15 (up to 15 samples per run)	23
BioSprint 96 DNA Plant Kit	Magnetic particles; up to 50 mg tissue; automated on BioSprint 96 (up to 96 samples per run)	23

* No longer available.

Table 6. Kits for simultaneous purification of multiple analytes from animal or human tissues

Analytes purified	Kit	Kit format	Page
DNA, RNA, and protein	AllPrep® DNA/RNA/ Protein Mini Kit	Spin column; up to 30 mg tissue	16
DNA and RNA	AllPrep DNA/RNA Micro Kit	Spin column; up to 5 mg tissue	16
	AllPrep DNA/RNA Mini Kit	Spin column; up to 30 mg tissue	16

QIAGEN Supplementary Protocols

Many of the protocols listed in this handbook are supplementary to the protocols found in the handbook of the specific kit being used. QIAGEN is constantly developing new protocols for existing products. These supplementary protocols can be obtained by contacting one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit www.qiagen.com) or visiting our Technical Support Center at www.qiagen.com/Support . Supplementary protocols can be identified by their reference number, which is made up of 2 letters followed by 2 numbers (e.g., RY23 — *Isolation of total RNA from plants using the RNeasy 96 Kit*).

Note: All protocols for use with the Mixer Mill can be used on the TissueLyser, without modification.

Equipment and Reagents to Be Supplied by User

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate material safety data sheets (MSDSs), available from the product supplier.

For all protocols

- Kit for purification of DNA and/or RNA (see ordering information on pages 31–36 or visit www.qiagen.com)
- Optional: Reagent DX (see page 15 for details)
- Optional: Liquid nitrogen or dry ice (see the individual protocols)

Disruption of 2 x 48 samples

- TissueLyser Adapter Set 2 x 24*
- 2 ml microcentrifuge tubes (e.g., Eppendorf® Safe-Lock micro test tubes†)
- Stainless steel or tungsten carbide beads*
- Optional: TissueLyser Single-Bead Dispenser, 5 mm* or TissueLyser Single-Bead Dispenser, 7 mm*

Disruption of 2 x 96 samples

- TissueLyser Adapter Set 2 x 96*
- Collection Microtubes (racked)*
- Collection Microtube Caps*
- Optional: TissueLyser 3 mm Bead Dispenser, 96-Well* or TissueLyser 5 mm Bead Dispenser, 96-Well*

Disruption of 2 large samples

- For disruption of hard samples and disruption in liquid nitrogen: Grinding Jar Set, S. Steel*
- For disruption of most samples: Grinding Jar Set, Teflon*

* See page 31 for ordering information.

† This is not a complete list of suppliers and does not include many important vendors of biological supplies.

Important Notes

General remarks on disruption and homogenization

Efficient disruption and homogenization of the starting material is an absolute requirement for all nucleic acid purification procedures. Disruption and homogenization are 2 distinct steps:

- **Disruption**: Complete disruption of cell walls and plasma membranes of cells and organelles is absolutely required to release all the nucleic acids contained in the sample. Different samples require different methods to achieve complete disruption. Incomplete disruption results in significantly reduced DNA and RNA yields.
- **Homogenization**: Homogenization is necessary to reduce the viscosity of the cell lysates produced by disruption. Homogenization shears the high-molecular-weight cellular proteins and carbohydrates to create a homogeneous lysate. Incomplete homogenization results in inefficient binding of nucleic acids to QIAGEN silica membranes and magnetic particles and therefore significantly reduced DNA and RNA yields.

Cellular disruption is one of the most critical steps in nucleic acid purification. Disruption in lysis buffer alone, without physical shearing, may result in nucleic acid degradation by endogenous DNases and RNases. Incomplete disruption prevents the lysis buffer, which inactivates nucleases, from contacting nucleic acids within the intact cells. Furthermore, cellular debris that is not disrupted can result in decreased yield and increases the risk of clogging the purification column. After sample disruption, there should be no visible particulates (except when disrupting materials containing hard, noncellular components, such as connective tissue, bone, or woody plant tissue). QIAGEN kits and protocols contain recommendations for the most appropriate method of sample disruption and homogenization to maximize the yield and quality of your DNA and RNA preparation.

Disruption and homogenization using the TissueLyser

In bead-milling, cells and tissues can be disrupted by rapid agitation in the presence of beads. Disruption and simultaneous homogenization occur by the shearing and crushing action of the beads as they collide with the sample. Disruption efficiency is influenced by:

- Size and composition of beads
- Ratio of buffer to samples (if buffer is used)
- Amount of starting material
- Configuration of TissueLyser (i.e., speed and duration)
- Consistency of sample
- Type of disruption vessel

Disruption and homogenization methods

When using the TissueLyser in combination with QIAGEN sample purification kits, one of 2 methods for disruption and homogenization is carried out: samples are either disrupted and homogenized in lysis buffer at room temperature, or precooled and then disrupted and homogenized without lysis buffer. With the latter method, lysis buffer is added after disruption and homogenization.

The method of precooling samples depends on the TissueLyser accessory used. If using the TissueLyser Adapter Set 2 x 24 or TissueLyser Adapter Set 2 x 96, the adapter set should be stored at –80°C for at least 2 hours prior to starting disruption and homogenization, and the tubes containing the samples should be precooled on dry ice. If using a Grinding Jar Set, the jar containing the sample can be frozen in liquid nitrogen prior to starting disruption and homogenization.

Important: When using a TissueLyser Adapter Set, do not freeze the adapter set or the sample tubes in liquid nitrogen, as this may result in breakage of the tubes.

In special cases (e.g., the disruption of teeth or plant seeds), the sample can be disrupted and homogenized at room temperature without lysis buffer, although this increases the risk of nucleic acid degradation by nucleases.

Bead selection

For disruption of small samples, the optimal beads to use are 0.1–0.6 mm (mean diameter) glass beads for bacteria, 0.5 mm glass beads for yeast and unicellular animal cells, and 3–7 mm stainless steel or tungsten carbide beads for plant and animal/human tissues. It is essential that glass beads are pretreated before use by washing in concentrated nitric acid.* Pretreated (acid-washed) beads can be purchased from many vendors of biological supplies (e.g., Sigma, cat. nos. G1145, G1277, and G8772†). Disruption parameters for samples not addressed in this handbook must be determined empirically. For disruption of large samples, a Grinding Jar Set can be used, which is supplied with either stainless steel grinding balls (for disrupting hard samples such as bone or for disrupting samples in liquid nitrogen) or Teflon grinding balls (for disrupting most samples).

Note: Do not use Buffer RLT, Buffer RLT Plus, or QIAzol® Lysis Reagent in conjunction with tungsten carbide beads. These buffers react chemically with tungsten carbide, causing damage to the bead surface.

* When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate material safety data sheets (MSDSs), available from the product supplier.

† This is not a complete list of suppliers and does not include many important vendors of biological supplies.

Operating the TissueLyser

The TissueLyser Adapter Set or Grinding Jar Set should be securely fixed into the clamps (arms) of the TissueLyser. For details, refer to the operating instructions supplied with the TissueLyser.

Disruption is carried out in high-speed (20–30 Hz) shaking steps. Disruption for 2 x 3 minutes at 20–30 Hz is usually sufficient to release RNA. If disrupting samples for subsequent DNA purification, disruption times should be shorter in order to prevent DNA shearing.

When using a TissueLyser Adapter Set, samples nearer to the TissueLyser move more slowly than samples further away from the TissueLyser. To ensure uniform disruption and homogenization, 2 shaking steps should be carried out. After the first shaking step, the TissueLyser Adapter Set should be disassembled and the rack of tubes should be rotated so that the tubes that were nearest to the TissueLyser are now outermost. The TissueLyser Adapter Set should then be reassembled before continuing with the second shaking step.

For optimal operation, the TissueLyser should always be balanced. A balance can be provided by assembling a second TissueLyser Adaptor Set with a rack of tubes containing only disruption beads, and fixing this adaptor set into the empty clamp. If using grinding jars, the balance should consist of a second grinding jar containing a grinding ball.

Disruption and homogenization in Buffer RLT Plus

RNeasy Plus Kits and certain AllPrep Kits are supplied with Buffer RLT Plus, a lysis buffer that provides optimal sample lysis as well as appropriate conditions for DNA binding to gDNA Eliminator columns or AllPrep DNA columns. When disrupting and homogenizing tissues in Buffer RLT Plus, excessive foaming may occur. This foaming is substantially reduced by adding Reagent DX to Buffer RLT Plus at a final concentration of 0.5% (v/v) before starting disruption and homogenization. Reagent DX has been carefully tested with RNeasy Plus Kits and AllPrep Kits, and has no effect on RNA purity or on downstream applications such as real-time RT-PCR. Buffer RLT Plus containing Reagent DX can be stored at room temperature (15–25°C) for at least 9 months. Reagent DX is supplied separately; for ordering information, see page 32.

Protocol: Purification of RNA or Multiple Analytes from Animal and Human Tissues

This protocol provides guidelines on disrupting animal and human tissues for purification of RNA or for simultaneous purification of DNA and RNA or DNA, RNA, and protein. If using a QIAGEN sample purification kit (see Tables 1, 2, and 6 on pages 7, 8, and 10), refer to the supplied handbook, which contains a complete protocol for sample disruption and purification.

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using a QIAGEN sample purification kit, read the supplied handbook carefully before starting.
- After storage in RNA*later* RNA Stabilization Reagent or Allprotect Tissue Reagent, tissues become slightly hard. If disrupting in Buffer RLT, we recommend increasing the volume of this buffer according to the protocols in the *RNeasy Mini Handbook*. In addition, the disruption time may be need to be extended.

Procedure

1. **Place the tissues in 2 ml microcentrifuge tubes or 1.2 ml collection microtubes containing 1 stainless steel bead (3–7 mm mean diameter).**

   If handling fresh or frozen tissue samples, keep the tubes on dry ice.

2. **Place the tubes at room temperature (15–25°C). Immediately add the appropriate volume of lysis buffer (e.g., Buffer RLT, Buffer RLT Plus, or QIAzol Lysis Reagent) to each tube.**

   Note: Do not use Buffer RLT, Buffer RLT Plus, or QIAzol Lysis Reagent with tungsten carbide beads, as these buffers can react with and damage the bead surface.

   Note: If using Buffer RLT Plus, we recommend adding Reagent DX to prevent excessive foaming. For details, see "Disruption and homogenization in Buffer RLT Plus" (page 15).

3. **Place the tubes in the TissueLyser Adapter Set 2 x 24 (if using 2 ml tubes) or the TissueLyser Adapter Set 2 x 96 (if using 1.2 ml tubes).**

4. **Operate the TissueLyser for 2 min at 20–30 Hz. Disassemble the adapter set, rotate the rack of tubes so that the tubes nearest to the TissueLyser are now outermost, and reassemble the adapter set. Operate the TissueLyser for another 2 min at 20–30 Hz.**

   The duration of disruption and homogenization depends on the tissue being processed and can be extended until no tissue debris is visible.

   Rearranging the tubes ensures uniform disruption and homogenization.

   If processing fiber-rich tissues, complete disruption and homogenization may sometimes not be possible. However, small amounts of debris have no effect on subsequent RNA purification with QIAGEN kits and are usually digested in the proteinase K step.

5. **Proceed with RNA, DNA/RNA, or DNA/RNA/protein purification.**

   Do not reuse the stainless steel beads.

Protocol: Purification of RNA from Plant Tissues

This protocol provides guidelines on disrupting plant tissues for subsequent RNA purification. If using a QIAGEN kit for RNA purification (see Table 3, page 9), refer to the supplied handbook, which contains a complete protocol for sample disruption and RNA purification.*

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using a QIAGEN kit for RNA purification, read the supplied handbook carefully before starting.
- Soft, fresh tissues from plants such as Nicotiana and Arabidopsis can often be disrupted and homogenized in lysis buffer. Hard tissues (e.g., woody plant materials) may require freezing and disruption under frozen conditions.

Procedure

1. **If handling frozen tissues, precool the TissueLyser Adapter Set 2 x 24 or TissueLyser Adapter Set 2 x 96 by storing at –80°C for at least 2 h.**

   The adapter sets do not need to be precooled if handling fresh tissues.

2. **Place the tissues in 2 ml microcentrifuge tubes or 1.2 ml collection microtubes containing 1 stainless steel bead (3–7 mm mean diameter). If handling frozen tissues, keep the tubes on dry ice.**

   Note: Do not freeze the tubes in liquid nitrogen, as this may lead to breakage of the tubes.

3. **Immediately add the appropriate volume of lysis buffer (e.g., Buffer RLT or Buffer RLC) to each tube. If handling frozen tissues, do not add lysis buffer.**

   Note: Do not use Buffer RLT or Buffer RLC with tungsten carbide beads, as these buffers can react with and damage the bead surface.

4. **Place the tubes in the TissueLyser Adapter Set 2 x 24 (if using 2 ml tubes) or the TissueLyser Adapter Set 2 x 96 (if using 1.2 ml tubes).**

* If using the RNeasy 96 Kit, refer to supplementary protocol *Isolation of total RNA from plants using the RNeasy 96 Kit* (RY23).

5. **Operate the TissueLyser for 1 min at 30 Hz. Disassemble the adapter set, rotate the rack of tubes so that the tubes nearest to the TissueLyser are now outermost, and reassemble the adapter set. Operate the TissueLyser for another 1 min at 30 Hz.**

   The duration of disruption and homogenization depends on the tissue being processed and can be extended until no tissue debris is visible. If necessary, keep the samples on dry ice for several minutes in between the individual disruption steps to avoid thawing of the samples.

   Rearranging the tubes ensures uniform disruption and homogenization.

6. **Proceed with RNA purification. If frozen samples were disrupted, add lysis buffer, and proceed with RNA purification.**

   Do not reuse the stainless steel beads.

Protocol: Purification of RNA from Bacteria

This protocol provides guidelines on disrupting bacteria for subsequent RNA purification. If using an RNeasy Protect Bactera Kit for RNA purification (see Table 3, page 9), refer to the supplied *RNAprotect® Bacteria Reagent Handbook*, which contains complete protocols for sample disruption and RNA purification.

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using an RNeasy Protect Bacteria Kit for RNA purification, read the supplied handbook carefully before starting.
- Bead milling will disrupt most Gram-positive and Gram-negative bacteria, including mycobacteria. Gram-positive bacteria usually require more rigorous digestion (e.g., increased enzyme digestion time and temperature) and mechanical treatment than Gram-negative bacteria. For details, see the *RNAprotect Bacteria Reagent Handbook*.

Procedure

1. **Pellet the bacterial cells by centrifugation. Immediately add the appropriate volume of lysis buffer (e.g., Buffer RLT) to each sample and vortex vigorously.**
2. **Transfer each sample to 2 ml microcentrifuge tubes containing 25–50 mg acid-washed glass beads (150–600 µm mean diameter).**
3. **Place the tubes in the TissueLyser Adapter Set 2 x 24.**
4. **Operate the TissueLyser for 5 min at 30 Hz.**

   The duration of disruption and homogenization depends on the sample being processed and can be extended until no debris is visible.
5. **Proceed with RNA purification.**

Protocol: Purification of RNA from Yeast

This protocol provides guidelines on disrupting yeast cells for subsequent RNA purification. If using the RNeasy Mini Kit for RNA purification (see Table 3, page 9), refer to the supplied *RNeasy Mini Handbook*, which contains a complete protocol for sample disruption and RNA purification.

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using the RNeasy Mini Kit for RNA purification, read the supplied handbook carefully before starting.

Procedure

1. **Pellet the yeast cells by centrifugation. Immediately add the appropriate volume of lysis buffer (e.g., Buffer RLT) to each sample and vortex vigorously.**
2. **Transfer each sample to 2 ml microcentrifuge tubes containing 600 µl acid-washed glass beads (450–550 µm mean diameter).**
3. **Place the tubes in the TissueLyser Adapter Set 2 x 24.**
4. **Operate the TissueLyser for 5 min at 30 Hz.**

   The duration of disruption and homogenization depends on the sample being processed and can be extended until no debris is visible.
5. **Proceed with RNA purification.**

Protocol: Purification of DNA from Animal and Human Tissues

This protocol provides guidelines on disrupting animal and human tissues for subsequent DNA purification. If using a QIAGEN kit for DNA purification (see Table 4, page 9), refer to the following supplementary protocols for the complete procedure for sample disruption and DNA purification:

- **DNeasy Blood & Tissue Kit**: *Purification of total DNA from soft tissues using the TissueLyser and the DNeasy Blood & Tissue Kit* (DY11)
- **QIAamp DNA Mini Kit**: *Isolation of DNA from soft tissues using the TissueLyser and QIAamp DNA Mini Kit* (QA31)
- **EZ1 DNA Tissue Kit**: *Isolation of DNA from soft tissue using the TissueLyser and EZ1 DNA Tissue Kit* (MA23)
- **MagAttract DNA Mini M48 Kit**: *Isolation of DNA from soft tissue using the TissueLyser and MagAttract Mini M48 Kit* (MA22)

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using a QIAGEN kit for DNA purification, read the supplied handbook and appropriate supplementary protocol carefully before starting.

Procedure

1. **Place the tissues in 2 ml microcentrifuge tubes containing 1 stainless steel bead (5 mm mean diameter).**
2. **Add the appropriate volume of lysis buffer (e.g., Buffer ATL) to each tube.**
3. **Place the tubes in the TissueLyser Adapter Set 2 x 24.**
4. **Operate the TissueLyser for 20 s at 15 Hz.**

   Note: Exceeding this homogenization time and intensity may lead to significant fragmentation of genomic DNA.

   If working with fibrous tissues, cutting the tissue into smaller pieces before starting disruption will improve disruption efficiency.
5. **Proceed with DNA purification.**

Protocol: Purification of DNA from Plant Tissues (Mini Protocol)

This protocol provides guidelines on using TissueLyser Adapter Sets to disrupt plant tissues for subsequent DNA purification. If using a QIAGEN kit for DNA purification (see Table 5, page 10), refer to the supplied handbook, which contains a complete protocol for sample disruption and DNA purification.

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using a QIAGEN kit for DNA purification, read the supplied handbook carefully before starting.
- Fresh, frozen, or lyophilized tissues can be processed. Fresh tissues can be disrupted in lysis buffer at ambient temperature. Alternatively, fresh or frozen tissues can be disrupted without lysis buffer if they are precooled on dry ice and if the adapter sets are precooled at –80°C for at least 2 h. Lyophilized tissues can be disrupted without lysis buffer at ambient temperature. Disruption of tissues in lysis buffer yields DNA ideal for PCR, while disruption of tissues in liquid nitrogen yields DNA of a higher molecular weight. We do not recommend disrupting frozen tissues in lysis buffer as this results in low yields and degraded DNA.

Procedure

1. **If purifying DNA of higher molecular weight from fresh or frozen tissues, precool the TissueLyser Adapter Set 2 x 24 or TissueLyser Adapter Set 2 x 96 by storing at –80°C for at least 2 h.**

   The adapter sets do not need to be precooled if disrupting fresh tissues in lysis buffer or if disrupting lyophilized tissues.

2. **Place the tissues in 2 ml microcentrifuge tubes or 1.2 ml collection microtubes containing 1 tungsten carbide bead (3 mm mean diameter).**

3. **If purifying DNA of higher molecular weight from fresh or frozen tissues, precool the tubes by storing on dry ice.**

   Note: Do not freeze the tubes in liquid nitrogen, as this may lead to breakage of the tubes.

   The tubes do not need to be precooled if disrupting fresh tissues in lysis buffer or if disrupting lyophilized tissues.

4. **If necessary, add an appropriate volume of lysis buffer (e.g., Buffer AP1) to each tube.**

   Lysis buffer must not be added if disrupting precooled tissues or if disrupting lyophilized tissues.

5. **Place the tubes in the TissueLyser Adapter Set 2 x 24 (if using 2 ml tubes) or TissueLyser Adapter Set 2 x 96 (if using 1.2 ml tubes).**

6. **Operate the TissueLyser for 1 min at 25 Hz. Disassemble the adapter set, rotate the rack of tubes so that the tubes nearest to the TissueLyser are now outermost, and reassemble the adapter set. Operate the TissueLyser for another 1 min at 25 Hz.**

   Note: If processing precooled tissues, increasing the disruption time may lead to thawing and reduced DNA yield and quality.

7. **Add lysis buffer (e.g., Buffer AP1) if necessary, and proceed with DNA purification.**

   The tungsten carbide beads can be reused. For details on recovering and cleaning beads, refer to the *DNeasy Plant Handbook*.

Protocol: Purification of DNA from Plant Tissues (Maxi Protocol)

This protocol provides guidelines on using a Grinding Jar Set to disrupt plant tissues for subsequent DNA purification. If using the DNeasy Plant Maxi Kit for DNA purification (see Table 5, page 10), refer to the supplied *DNeasy Plant Handbook*, which contains a complete protocol for sample disruption and DNA purification.

Important points before starting

- Before beginning the procedure, read "Important Notes" (page 13).
- Ensure that you are familiar with operating the TissueLyser by referring to the operating instructions.
- If using the DNeasy Plant Maxi Kit for DNA purification, read the supplied handbook carefully before starting.
- Fresh, frozen, or lyophilized tissues can be processed. Fresh tissues can be disrupted in lysis buffer at ambient temperature. Alternatively, fresh or frozen tissues can be disrupted without lysis buffer if the jar containing the sample is frozen in liquid nitrogen. Lyophilized tissues can be disrupted without lysis buffer at ambient temperature. Disruption of tissues in lysis buffer yields DNA ideal for PCR, while disruption of tissues frozen in liquid nitrogen yields DNA of a higher molecular weight. We do not recommend disrupting frozen tissues in lysis buffer as this results in low yields and degraded DNA.

Procedure

1. **Place the tissues in 10 ml grinding jars containing 1 stainless steel grinding ball (20 mm mean diameter).**
2. **If purifying DNA of higher molecular weight from fresh or frozen tissues, freeze the jars in liquid nitrogen for 1 min.**

   The grinding jars do not need to be frozen if disrupting fresh tissues in lysis buffer or if disrupting lyophilized tissues.
3. **If necessary, add an appropriate volume of lysis buffer (e.g., Buffer AP1) to each jar.**

   Lysis buffer must not be added if processing frozen grinding jar sets or if disrupting lyophilized tissues.
4. **Operate the TissueLyser for 1 min at 30 Hz.**
5. **If purifying DNA of higher molecular weight from fresh or frozen tissues, freeze the jars in liquid nitrogen for 1 min.**

   The grinding jars do not need to be frozen if disrupting fresh tissues in lysis buffer or if disrupting lyophilized tissues.

6. **Operate the TissueLyser for 1 min at 30 Hz.**
7. **Add lysis buffer (e.g., Buffer AP1) if necessary, and proceed with DNA purification.**

   The stainless steel grinding balls can be reused. For details on recovering and cleaning grinding balls, refer to the *DNeasy Plant Handbook*.

Appendix A: TissueLyser Accessories

TissueLyser Adapter Set 2 x 24

This adapter set allows disruption of 48 (2 x 24) samples in parallel using standard 2 ml microcentrifuge tubes (e.g., Eppendorf Safe-Lock micro test tubes). Sample disruption can be carried out at room temperature or after storing the adapter set at –80°C for at least 2 hours. The adapter set can be cleaned with detergent, microbicides, or up to 96% ethanol. For more information, see the product sheet supplied with the TissueLyser Adapter Set.

TissueLyser Adapter Set 2 x 96

This adapter set allows disruption of 192 (2 x 96) samples in parallel using Collection Microtubes (racked). Sample disruption can be carried out at room temperature or after storing the adapter set at –80°C for at least 2 hours. The adapter set can be cleaned with detergent, microbicides, or up to 96% ethanol. For more information, see the product sheet supplied with the TissueLyser Adapter Set.

TissueLyser Single-Bead Dispenser, 5 mm

This bead dispenser dispenses individual beads (5 mm diameter) into any sample container. The reservoir holds approximately 150 beads. The TissueLyser Single-Bead Dispenser can be cleaned with water or detergent. For more information, see the product sheet supplied with the TissueLyser Single-Bead Dispenser.

TissueLyser Single-Bead Dispenser, 7 mm

This bead dispenser dispenses individual beads (7 mm diameter) into any sample container. The reservoir holds approximately 45 beads. The TissueLyser Single-Bead Dispenser can be cleaned with water or detergent. For more information, see the product sheet supplied with the TissueLyser Single-Bead Dispenser.

TissueLyser 3 mm Bead Dispenser, 96-well

This bead dispenser dispenses 96 beads (3 mm diameter) in parallel into Collection Microtubes (racked), enabling high-throughput disruption and homogenization. The reservoir holds approximately 1000 beads. The dispenser can be cleaned with water or detergent. For more information, see the product sheet supplied with the TissueLyser Bead Dispenser, 96-well.

TissueLyser 5 mm Bead Dispenser, 96-well

This bead dispenser dispenses 96 beads (5 mm diameter) in parallel into Collection Microtubes (racked), enabling high-throughput disruption and homogenization. The reservoir holds approximately 300 beads. The dispenser can be cleaned with water or detergent. For more information, see the product sheet supplied with the TissueLyser Bead Dispenser, 96-well.

Grinding Jar Set, S. Steel

The grinding jars allow disruption of 2 large samples in parallel using stainless steel grinding balls. Sample disruption can be carried out at room temperature or after freezing the grinding jars in liquid nitrogen. For more information, see the product sheet supplied with the Grinding Jar Set.

Grinding Jar Set, Teflon

The grinding jars allow disruption of 2 large samples in parallel using Teflon grinding balls. Sample disruption can be carried out at room temperature. For more information, see the product sheet supplied with the Grinding Jar Set.

Appendix B: Automated Solutions

Automated purification using QIAGEN spin-column kits

Purification of genomic DNA or total RNA from tissues can be fully automated on the QIAcube. The innovative QIAcube uses advanced technology to process QIAGEN spin columns, enabling seamless integration of automated, low-throughput sample prep into your laboratory workflow. Sample preparation using the QIAcube follows the same steps as the manual procedure (i.e., lyse, bind, wash, and elute), enabling you to continue using DNeasy Kits, QIAamp Kits, RNeasy Kits, and the miRNeasy Mini Kit for purification of high-quality DNA or RNA. For more information about the automated procedure, see the relevant protocol sheet available at www.qiagen.com/MyQIAcube .

The QIAcube.

The QIAcube is preinstalled with protocols for purification of plasmid DNA, genomic DNA, RNA, viral nucleic acids, and proteins, plus DNA and RNA cleanup. The range of protocols available is continually expanding, and additional QIAGEN protocols can be downloaded free of charge at www.qiagen.com/MyQIAcube .

Automated purification using magnetic particles and 96-well plates

Complete automated solutions from QIAGEN allow purification of genomic DNA or total RNA from human, animal, or plant tissues at a range of different throughputs using magnetic particles or 96-well plates (see Table 7, page 30). QIAGEN Instrument Service provides comprehensive support services to ensure the continued success of your automated applications. For more information about QIAGEN automation and QIAGEN Instrument Service, visit www.qiagen.com/automation .

Table 7. Automated purification of genomic DNA and total RNA from tissues

Workstation	Capability
EZ1 Advanced	Purification of genomic DNA or total RNA from 1–6 human samples per run
QIAsymphony SP	Purification of genomic DNA or total RNA from 1–96 animal or human samples per run
BioRobot Universal System	Purification of genomic DNA or total RNA in 96-well format from animal or human samples, plus downstream reaction setup
BioSprint 96	Purification of genomic DNA from up to 96 animal or plant samples per run

Low-throughput sample disruption

The TissueRuptor® is a handheld rotor–stator homogenizer that provides rapid and efficient disruption of individual samples for a wide range of downstream applications. The TissueRuptor uses transparent disposable probes, which helps to minimize the risk of cross-contamination and enables visual control of the sample disruption process. The TissueRuptor is an integral part of QIAGEN's complete solution for tissue management in gene expression, genotyping, and proteomics applications. Optimized protocols are available for sample disruption prior to manual or automated nucleic acid or protein purification, enabling a streamlined, efficient workflow. Purification of RNA, DNA, total nucleic acids, or protein can then be performed using QIAGEN kits. For more information about the TissueRuptor, visit www.qiagen.com/TissueRuptor .

Automated multicapillary gel electrophoresis

The revolutionary QIAxcel System enables fully automated and sensitive, high-resolution capillary electrophoresis for up to 96 samples per run. Ready-to-go gel cartridges reduce manual handling errors and eliminate the need for tedious gel preparation. With the QIAxcel System, analysis of DNA fragments, single- or multiplex PCR products, and qualitative and quantitative RNA analysis is now easier and faster than ever. To find out more, visit www.qiagen.com/QIAxcel .

Ordering Information

Product	Contents	Cat. no.
TissueLyser II	Universal laboratory mixer-mill disruptor, 100–120/220–240 V, 50/60 Hz	85300
Accessories		
TissueLyser Adapter Set 2 x 24	2 sets of Adapter Plates and 2 racks for use with 2 ml microcentrifuge tubes on the TissueLyser	69982
TissueLyser Adapter Set 2 x 96	2 sets of Adapter Plates for use with Collection Microtubes (racked) on the TissueLyser	69984
Grinding Jar Set, S. Steel (2 x 10 ml)	2 Grinding Jars (10 ml), 2 Stainless Steel Grinding Balls (20 mm)	69985
Grinding Jar Set, Teflon (2 x 10 ml)	2 Grinding Jars (10 ml), 2 Teflon Grinding Balls (20 mm)	69986
Stainless Steel Beads, 5 mm (200)	Stainless Steel Beads, suitable for use with the TissueLyser system	69989
Tungsten Carbide Beads, 3 mm (200)	Tungsten Carbide Beads, suitable for use with the TissueLyser system	69997
TissueLyser Single-Bead Dispenser, 5 mm	For dispensing individual beads (5 mm diameter)	69965
TissueLyser Single-Bead Dispenser, 7 mm	For dispensing individual beads (7 mm diameter)	69967
TissueLyser 3 mm Bead Dispenser, 96-Well	For dispensing 96 beads (3 mm diameter) in parallel	69973
TissueLyser 5 mm Bead Dispenser, 96-Well	For dispensing 96 beads (5 mm diameter) in parallel	69975
Collection Microtubes (racked)	Nonsterile polypropylene tubes (1.2 ml), 960 in racks of 96	19560
Collection Microtube Caps	Nonsterile polypropylene caps for collection microtubes (1.2 ml) and round-well blocks, 960 in strips of 8	19566

Ordering Information

Product	Contents	Cat. no.
Related products		
RNeasy Kits — for purification of total RNA from cells, tissues, and yeast		
RNeasy Micro Kit (50)	For 50 preps: RNeasy MinElute® Spin Columns, Collection Tubes, DNase I, Carrier RNA, Buffers	74004
RNeasy Mini Kit (50)	For 50 preps: RNeasy Spin Columns, Collection Tubes, Buffers	74104
RNeasy Protect Kits — for stabilization and purification of total RNA from tissues		
RNeasy Protect Mini Kit (50)	For 50 preps: RNA*later* RNA Stabilization Reagent, RNeasy Spin Columns, Collection Tubes, Buffers	74124
RNeasy Plus Kits — for purification of total RNA from cells and tissues using gDNA Eliminator spin columns		
RNeasy Plus Micro Kit (50)	For 50 preps: RNeasy MinElute Spin Columns, gDNA Eliminator Spin Columns, Collection Tubes, Carrier RNA, Buffers	74034
RNeasy Plus Mini Kit (50)	For 50 preps: RNeasy Spin Columns, gDNA Eliminator Spin Columns, Collection Tubes, Buffers	74134
Reagent DX	1 ml Reagent DX in a screw-cap tube	19088
RNeasy Fibrous Tissue Kits — for purification of total RNA from fiber-rich tissues		
RNeasy Fibrous Tissue Mini Kit (50)	For 50 preps: RNeasy Spin Columns, Collection Tubes, Proteinase K, DNase I, Buffers	74704
RNeasy Fibrous Tissue Midi Kit (10)	For 10 preps: RNeasy Spin Columns, Collection Tubes, Proteinase K, DNase I, Buffers	75742
RNeasy Lipid Tissue Kits — for purification of total RNA from all types of tissue, including fatty tissues		
RNeasy Lipid Tissue Mini Kit (50)	For 50 preps: RNeasy Spin Columns, Collection Tubes, QIAzol Lysis Reagent, Buffers	74804

Ordering Information

Product	Contents	Cat. no.
RNeasy 96 Universal Tissue Kits — for purification of total RNA from all types of tissue in 96-well format		
RNeasy 96 Universal Tissue Kit (4)	For 4 x 96 preps: RNeasy 96 Plates, Elution Microtubes CL, Caps, S-Blocks, Airpore Tape Sheets, QIAzol Lysis Reagent, Buffers	74881
RNeasy 96 Universal Tissue 8000 Kit (12)	For 12 x 96 preps on the BioRobot Universal System: RNeasy 96 Plates, Collection Microtubes, Elution Microtubes CL, Caps, S-Blocks, QIAzol Lysis Reagent, Buffers	967852
EZ1 RNA Tissue Mini Kit — for purification of total RNA from easy-to-lyse tissues on the BioRobot EZ1 workstation		
EZ1 RNA Tissue Mini Kit (48)	For 48 preps: Reagent Cartridges, Tips, Tip-Holders, Tubes, DNase I, Buffer RLT	959034
EZ1 RNA Universal Tissue Kit — for purification of total RNA from all types of tissue on the BioRobot EZ1 workstation		
EZ1 RNA Universal Tissue Kit (48)	For 48 preps: Reagent Cartridges, Tips, Tip-Holders, Tubes, QIAzol Lysis Reagent	956034
MagAttract RNA Tissue Mini M48 Kit — for purification of total RNA from easy-to-lyse tissues on the BioRobot M48 workstation		
MagAttract RNA Tissue Mini M48 Kit (192)	For 192 preps: MagAttract Suspension E, DNase I, Buffers	959236
MagAttract RNA Universal Tissue M48 Kit — for purification of total RNA from all types of tissue on the BioRobot M48 workstation		
MagAttract RNA Universal Tissue M48 Kit (192)	For 192 preps: MagAttract Suspension E, DNase I, QIAzol Lysis Reagent, Buffers	956336
QIAsymphony RNA Kit — for purification of total RNA from cells and tissues on the QIAsymphony SP		
QIAsymphony RNA Kit (192)	For 192 preps: 2 Reagent Cartridges, and Enzyme Racks	931636

Ordering Information

Product	Contents	Cat. no.
RNeasy Plant Mini Kit — for purification of total RNA from plants and fungi		
RNeasy Plant Mini Kit (20)	For 20 preps: RNeasy Spin Columns, QIAshredder Spin Columns, Collection Tubes, Buffers	74903
RNeasy 96 Kit — for purification of total RNA from cells in 96-well format		
RNeasy 96 Kit (4)	For 4 x 96 preps: RNeasy 96 Plates, Elution Microtubes CL, Caps, S-Blocks, Airpore Tape Sheets, Buffers	74181
RNeasy Protect Bacteria Kits — for stabilization and purification of total RNA from bacteria		
RNeasy Protect Bacteria Mini Kit (50)	For 50 preps: RNAprotect Bacteria Reagent, RNeasy Mini Kit	74524
RNeasy Protect Bacteria Midi Kit (10)	For 10 preps: RNAprotect Bacteria Reagent, RNeasy Midi Kit	75552
AllPrep DNA/RNA/Protein Mini Kit — for simultaneous purification of DNA, RNA, and protein from cells and tissues		
AllPrep DNA/RNA/ Protein Mini Kit (50)	For 50 preps: AllPrep DNA Spin Columns, RNeasy Spin Columns, Collection Tubes, Buffers	80004
AllPrep DNA/RNA Kits — for simultaneous purification of DNA and RNA from cells and tissues		
AllPrep DNA/RNA Micro Kit (50)	For 50 preps: AllPrep DNA Spin Columns, RNeasy MinElute Spin Columns, Collection Tubes, Carrier RNA, Buffers	80284
AllPrep DNA/RNA Mini Kit (50)	For 50 preps: AllPrep DNA Spin Columns, RNeasy Spin Columns, Collection Tubes, Buffers	80204
QIAamp DNA Mini Kit — for purification of genomic, mitochondrial, bacterial, parasite, or viral DNA		
QIAamp DNA Mini Kit (50)	For 50 preps: QIAamp Spin Columns, Collection Tubes, Proteinase K, Buffers	51304

Ordering Information

Product	Contents	Cat. no.
EZ1 DNA Tissue Kit — for automated purification of genomic DNA from 1–6 human samples on the BioRobot EZ1 workstation		
EZ1 DNA Tissue Kit (48)	For 48 preps: Reagent Cartridges, Tips, Tip-Holders, Tubes, Proteinase K, Buffer G2	953034
MagAttract DNA Mini M48 Kit — for automated purification of genomic DNA from 6–48 human samples on the BioRobot M48 workstation		
MagAttract DNA Mini M48 Kit (192)	For 192 preps: MagAttract Suspension B, Proteinase K, Buffers	953336
QIAsymphony DNA Kits — for purification of DNA from a wide range of sample types on the QIAsymphony SP		
QIAsymphony DNA Mini Kit (96)	For 96 preps of 400 µl each: 2 Reagent Cartridges, and Enzyme Racks	931235
QIAsymphony DNA Midi Kit (96)	For 96 preps of 1000 µl each: 2 Reagent Cartridges, and Enzyme Racks	931255
DNeasy Blood & Tissue Kit — for purification of total DNA from animal blood and tissues, and from cells, yeast, bacteria, or viruses		
DNeasy Blood & Tissue Kit (50)	For 50 preps: DNeasy Spin Columns, Collection Tubes, Proteinase K, Buffers	69504
DNeasy 96 Blood & Tissue Kit — for purification of total DNA from animal blood and tissues, and from cells, yeast, bacteria, or viruses in 96-well format		
DNeasy 96 Blood & Tissue Kit (4)	For 4 x 96 preps: DNeasy 96 Plates, Collection Microtubes, Caps, S-Blocks, Elution Microtubes RS, AirPore Tape Sheets, Proteinase K, Buffers	69581
DNeasy Plant Kits — for purification of total DNA from plants and fungi		
DNeasy Plant Mini Kit (50)	For 50 preps: DNeasy Spin Columns, QIAshredder Spin Columns, Collection Tubes, RNase A, Buffers	69104

Ordering Information

Product	Contents	Cat. no.
DNeasy Plant Maxi Kit (6)	For 6 preps: DNeasy Spin Columns, QIAshredder Spin Columns, Collection Tubes, RNase A, Buffers	68161
DNeasy 96 Plant Kit — for purification of total DNA from plants in 96-well format		
DNeasy 96 Plant Kit (6)	For 6 x 96 preps: DNeasy 96 Plates, Collection Microtubes, Caps, S-Blocks, Elution Microtubes RS, AirPore Tape Sheets, RNase A, Reagent DX, Buffers	69181
MagAttract 96 DNA Plant Core Kit — for manual or automated purification of total DNA from plants in 96-well format		
MagAttract 96 DNA Plant Core Kit (6)	For 6 x 96 preps: MagAttract Suspension A, RNase A, Buffers	67161
BioSprint 15 DNA Plant Kit — for automated purification of total DNA from plant tissue on the BioSprint 15 workstation		
BioSprint 15 DNA Plant Kit (60)	For 60 preps: MagAttract Suspension G, Rod Covers, Tube Strips, RNase A, Buffers	941514
BioSprint 96 DNA Plant Kit — for automated purification of total DNA from plant tissue on the BioSprint 96 workstation		
BioSprint 96 DNA Plant Kit (576)	For 576 preps: MagAttract Suspension G, Rod Covers, Microplates MP, S-Blocks, RNase A, Buffer RPW	941557

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

Notes

Notes

www.qiagen.com

Australia ▪ Orders 1-800-243-800 ▪ Fax 03-9840-9888 ▪ Technical 1-800-243-066

Austria ▪ Orders 0800-28-10-10 ▪ Fax 0800/28-10-19 ▪ Technical 0800-28-10-11

Belgium ▪ Orders 0800-79612 ▪ Fax 0800-79611 ▪ Technical 0800-79556

Brazil ▪ Orders 0800-557779 ▪ Fax 55-11-5079-4001 ▪ Technical 0800-557779

Canada ▪ Orders 800-572-9613 ▪ Fax 800-713-5951 ▪ Technical 800-DNA-PREP (800-362-7737)

China ▪ Orders 86-21-3865-3865 ▪ Fax 86-21-3865-3965 ▪ Technical 800-988-0325

Denmark ▪ Orders 80-885945 ▪ Fax 80-885944 ▪ Technical 80-885942

Finland ▪ Orders 0800-914416 ▪ Fax 0800-914415 ▪ Technical 0800-914413

France ▪ Orders 01-60-920-926 ▪ Fax 01-60-920-925 ▪ Technical 01-60-920-930 ▪ Offers 01-60-920-928

Germany ▪ Orders 02103-29-12000 ▪ Fax 02103-29-22000 ▪ Technical 02103-29-12400

Hong Kong ▪ Orders 800 933 965 ▪ Fax 800 930 439 ▪ Technical 800 930 425

Ireland ▪ Orders 1800 555 049 ▪ Fax 1800 555 048 ▪ Technical 1800 555 061

Italy ▪ Orders 800-789-544 ▪ Fax 02-334304-826 ▪ Technical 800-787980

Japan ▪ Telephone 03-6890-7300 ▪ Fax 03-5547-0818 ▪ Technical 03-6890-7300

Korea (South) ▪ Orders 080-000-7146 ▪ Fax 02-2626-5703 ▪ Technical 080-000-7145

Luxembourg ▪ Orders 8002-2076 ▪ Fax 8002-2073 ▪ Technical 8002-2067

Mexico ▪ Orders 01-800-7742-639 ▪ Fax 01-800-1122-330 ▪ Technical 01-800-7742-436

The Netherlands ▪ Orders 0800-0229592 ▪ Fax 0800-0229593 ▪ Technical 0800-0229602

Norway ▪ Orders 800-18859 ▪ Fax 800-18817 ▪ Technical 800-18712

Singapore ▪ Orders 1800-742-4362 ▪ Fax 65-6854-8184 ▪ Technical 1800-742-4368

Spain ▪ Orders 91-630-7050 ▪ Fax 91-630-5145 ▪ Technical 91-630-7050

Sweden ▪ Orders 020-790282 ▪ Fax 020-790582 ▪ Technical 020-798328

Switzerland ▪ Orders 055-254-22-11 ▪ Fax 055-254-22-13 ▪ Technical 055-254-22-12

UK ▪ Orders 01293-422-911 ▪ Fax 01293-422-922 ▪ Technical 01293-422-999

USA ▪ Orders 800-426-8157 ▪ Fax 800-718-2056 ▪ Technical 800-DNA-PREP (800-362-7737)

QIAGEN

1064945 10/2010

Sample & Assay Technologies

Filtered Universal Pipette Tips

BOENMED manufactures FILTERED UNIVERSAL PIPETTE TIPS. The Pipette tips are essential tools in laboratories and scientific research, designed to work with pipettes for accurate and precise liquid handling.
Pipette tips with filter barrier protects pipettors and samples from contamination.
The filter tips block >99% of aerosols to prevent cross-contamination.
Hydrophobic filters contain no additives and will not absorb samples.
The Universal Filter Tips Pipettes fit most popular brands of pipettors.
Each hinged rack is individually sealed in plastic and has a tear strip for easy opening without sharp instruments.
RNase, DNase and Pyrogen Free.

Product: Sterile pipette tips with filter
Material: PP
Color: Clear
Volume:10ul-1250ul.
Package Style:
Bulked: 1000tips/bag, 10bags/ctn
Racked: 96tips/rack, 10racks/pk, 50racks/ctn

Cat No.	**Description**	**Qty/Case(pcs)**
640403	Racked filter tips,96tips/rack, sterile, 20ul	4800
640406	Racked filter tips,96tips/rack, sterile, 200ul	4800
640407	Racked filter tips,96tips/rack, sterile, 1000ul	4800

Eppendorf Pipette Tips

Eppendorf Pipette Tips

BOENMED manufactures EPPENDORF PIPETTE TIPS. The Eppendorf Pipette Tips made from medical grade PP material, excellent input and output accuracy, perfect match with pipettes, mainly used for sample liquid transferring.
Clean, hydrophobic surfaces reduce sample retention, and increase accuracy and reproducibility.
Tip orifice is precisely centered for directional accuracy.

Product: Pipette Tips, Eppendorf pipette tips, Eppendorf Pipette Micro Tips, Disposable pipette tips.
Application: Designed for use in a wide variety of pipetting applications, compatibility with Eppendorf Pipettors.
Material: PP material.
Size:10ul, 200ul, 1000ul
Color: Various color optional easy to identify
Sterility: Non sterile.

Cat No.	Description
640201	Eppendorf pipette tips,clear,10ul,1000tips/bag
640202	Eppendorf pipette tips,yellow,200ul,1000tips/bag
640203	Eppendorf pipette tips,blue,1000ul,500pcs/bag

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

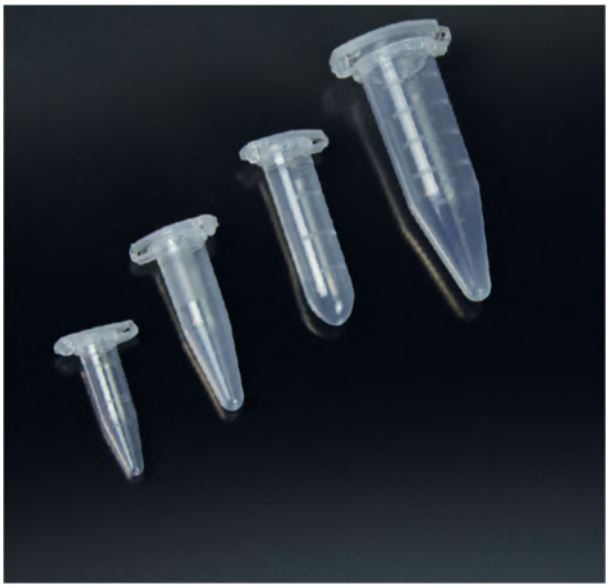
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
22.01.2025

MADE IN ITALY

ARTICOLO: **MICROPROVETTE SECURE LOCK**
ITEM: ***MICRO TEST TUBES SECURE LOCK***

DESCRIZIONE / *DESCRIPTION*



Microprovette con sistema di chiusura di sicurezza integrato nel tappo, per prevenirne l'apertura accidentale e l'evaporazione del campione. In polipropilene, graduate, con area di scrittura e tappo piatto perforabile. Sono certificate esenti da DNA umano, inibitori della PCR, ATP, DNasi, RNasi e pirogeni. Non citotossiche, non emolitiche. Idonee per applicazioni in PCR e in biologia molecolare. Sterili in confezione singola.
Temperatura di utilizzo: -80°C / +100°C.
Autoclavabili aperte a +121°C per 20 minuti.

Micro test tubes with secure lock integrated in the cap to prevent accidental cap opening and evaporation. In polypropylene, graduated, with writing area and flat pierceable cap. They are certified free of human DNA, PCR inhibitors, ATP, DNase, RNase and pyrogen. Non cytotoxic, non hemolytic. Suitable for PCR and molecular biology applications. Sterile individually wrapped..
Temperature of use: -80°C / +100°C.
Autoclavable open at +121°C for 20 minutes.

Prodotto con marchio CE - Prodotto marcato CE secondo quanto previsto dal Regolamento (UE) 2017/746
CE *Marked product - CE marked product according to Regulation (EU) 2017/746*

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / NOT *STERILE***	*Microbiological status*
Materiale impiegato	POLIPROPILENE / *POLYPROPYLENE*	*Raw material – container*
Temperature tollerate	MIN -80°C MAX +121°C	*Temperature range*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

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SECURE LOCK

Sistema di chiusura di sicurezza integrato nel tappo, per prevenirne l'apertura accidentale e l'evaporazione del campione.

Secure lock integrated in the cap to prevent accidental cap opening and evaporation

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" contenitore di campione" idoneo a contenere un campione biologico umano (per esempio urina, sangue, sperma, saliva, espettorato, pus, etc) al fine di effettuare analisi diagnostiche di laboratorio anche con tecniche di biologia molecolare. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale dei Dispositivi Medici (CND) > W050301020202 (Microprovette e coppette senza additivi in materiale plastico per analisi).
Classificazione EDMA > 51091001 - Other containers for samples of human origin
Basic UDI-DI (Global Model Number – GMN): 805577609F116MICPRBIO04DZ

Intended purpose is "IN VITRO MEDICAL DEVICE" "specimen receptacles" suitable to contain a human biological sample (e.g. urine, blood, sperm, saliva, sputum, pus, etc) in order to perform in vitro laboratory diagnostic analysis also with molecular biology techniques. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > W050301020202 (Samples analyses, plastic microtubes without additives).
EDMA code > 51091001 - Other containers for samples of human origin
Basic UDI-DI (Global Model Number – GMN): *805577609F116MICPRBIO04DZ*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

- Destinato esclusivamente ad uso professionale –

L'eventuale presenza di scala graduata è da intendersi a scopo indicativo e senza funzione metrologica
Non variare la destinazione d'uso. In caso di dubbio circa la destinazione d'uso, Vi preghiamo di contattare il Fabbricante.
Prima dell'utilizzo controllare la perfetta chiusura del dispositivo se applicabile
Manipolare utilizzando dispositivi di protezione individuale: pericolo di contaminazione
Non utilizzare il Dispositivo in caso di evidenti segni di rottura, lesioni, fessurazioni che potrebbero comprometterne il corretto uso
Non avvicinare il Dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare
Non utilizzare e smaltire il Dispositivo scaduto o con la confezione non integra
Non riutilizzare: Dispositivo monouso. L'eventuale riutilizzo potrebbe causare la contaminazione del campione.
Nel caso di dispositivo sterile o asettico: stato microbiologico garantito a confezione integra. Non ri-sterilizzare
Utilizzare il Dispositivo unicamente con accessori compatibili e/o in dotazione (tappi, supporti, ecc.)
Non esporre direttamente ai raggi solari; proteggere dall'umidità (U.R. max 75% a 26°C)
Conservare in luogo asciutto, temperatura min. -10°C (14°F) max +50°C (122°F)
Smaltire secondo le normative vigenti, pericolo di infezione.
Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.

- For professional use only -

Any presence of a graduated scale is intended for indicative purposes and without a metrological function.
Do not vary the intended purpose of the device. Please contact the Manufacturer in the evenience of doubts concerning the intended purpose.
Before use check the perfect closure of the device if applicable.
Handle using personal protective equipment: risk of contamination.
Do not use the Device in case of evident signs of breakage, injuries, cracks that could compromise its correct use.
Keep out of flame or heat sources which might damage the device.
Do not use after expiry date or if packing is opened.
Do not re-use: Disposable Device. Any reuse could cause sample contamination.
If sterile or aseptic Device: Microbiological status in undamaged pack. Do not re-sterilize.
Use the Device only with compatible and / or supplied accessories (caps, supports, etc.)
Do not put under direct sun rays; store in a dry, cool place (U.R. max 75% at 26°C)
Store in dry place, temperature range: min. -10°C (14°F) max +50°C (122°F)
Disposal according to applicable regulations, risk of infection.
Before use with particular substances check the resistance/compatibility chart in our catalogue.

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SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS* (UNI EN CEI ISO 15223-1)

CE Marchio CE *CE Mark*	IVD Dispositivo Medico Diagnostico in Vitro *In Vitro diagnostic medical device*	Consultare le istruzioni per l'uso *Consult instructions for use*
Data di produzione *Date of manufacture*	Data di scadenza *Use-by date*	LOT Lotto *Batch code*
REF Codice articolo *Catalogue number*	Fabbricante *Manufacturer*	Monouso *Do not re-use*
NON STERILE Non sterile *Non-sterile*	Proteggere dall'umidità *Keep dry*	Non esporre ai raggi del sole *Keep away from sunlight*

0.2 ml Real Time PCR tubes

Tubes made of polypropylene, featuring attached hinged caps.
Flat caps are easily pierceable and offer optical quality, thus allowing their application in **Real Time PCR.**
Available in strips of 8 tubes (see code **4095.1NP** in the following page).
Certified **RNAse, DNAse and PCR inhibitors free.**

code	description	case quantity	case weight	case volume
4094.5N	PCR 0.2 ml QPCR tube	1,000	0.25	0.003

0.2 ml PCR tubes

Tubes made of polypropylene, featuring attached hinged caps.
Caps are flat and easily pierceable.
See strips of these tubes on the following page (codes **4094.3N** and **4094.4N**).
Certified **RNAse, DNAse and PCR inhibitors free.**

code	colour	case quantity	case weight	case volume
4094.1N	natural	1,000	0.24	0.003
4094.1A	blue	1,000	0.24	0.003
4094.1R	red	1,000	0.24	0.003
4094.1AM	yellow	1,000	0.24	0.003

Ask for minimum quantity and delivery time for other colours.

0.2 ml PCR tubes

Made of polypropylene.
Tubes with attached domed cap.
Certified **RNAse, DNAse and PCR inhibitors free.**

code	description	colour	case quantity	case weight	case volume
4095.9N	individual tube with cap	natural	1,000	0.25	0.003

Microcentrifuge Tube

Microcentrifuge tube

BOENMED manufactures MICROCENTRIFUGE TUBE. The Microcentrifuge tubes are manufactured from robust virgin-polypropylene, clarity for better visual inspection.

-Flat cap with a beveled edge comfortable for opening and closing
-Precise lid sealing for lowest evaporation rates during storage
-Frosted writing area on tube for labeling and writing
-Clear molded graduations on tube for 1.5ml&2ml
-Flat top with a writable surface
-**RNase, DNase, DNA and Pyrogen free** available upon required.

Cat. No.	Description	Qty/Case
664101	0.5ml Microcentrifuge tube with snap cap, PP, clear	10000
664102	1.5ml Microcentrifuge tube with snap cap, PP, clear	5000
664103	**2.0ml Microcentrifuge tube with snap cap, PP, clear**	5000

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
14.01.2021

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **2120/SG**

DESCRIZIONE / *DESCRIPTION*

CONTENITORE GRADUATO PER URINE DA 150 ML
Tappo a vite inserito, in polietilene di colore rosso, che ne garantisce la perfetta tenuta con bordo zigrinato per una apertura e chiusura facile e sicura. Contenitore con superficie di scrittura. Ottima resistenza alle basse e alte temperature e buona resistenza agli agenti chimici. Prodotto in Polipropilene medicale (PP). Sterile, in confezione singola. Dispositivo Latex-Free e apirogeno. Conforme alla norma UNI EN 14254.

150 ML GRADUATED URINE CONTAINERS
Red inserted screw cap in polyethylene which guarantees the perfect leak-proof, with milled rim allowing a safe and easy opening/closing.
Container with writing surface. Excellent high and low temperatures resistance and chemical agents. Manufactured in medical PP. Sterile, individually wrapped. Latex free and pyrogen free device. Compliant with UNI EN 14254.

Prodotto con marchio CE - conforme alla Direttiva 98/79/CE e al D.lgs 332 del 08/09/2000

CE *Marked product* - *manufactured in compliance with 98/79/CE Directive and D.lgs 332 dtd 08/09/2000*

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**STERILE / *STERILE*** **RAGGI BETA / *BETA RAYS***	*Microbilogical status*
Materiale impiegato contenitore	POLIPROPILENE / *POLYPROPYLENE*	*Raw material – container*
Materiale impiegato tappo	POLIETILENE / *POLYETHYLENE*	*Raw material - cap*
Volume nominale contenitore (ml)	150	*Nominal volume container (ml)*
Scala graduata	MIN. 20ML – MAX 100ML	*Graduated scale*
Incrementi scala graduata (ml)	20	*Intervals graduated scale (ml)*
Temperature tollerate contenitore	MIN -10°C MAX +120°C	*Temperature range - container*
Temperature tollerate tappo	MIN -50°C MAX +80°C	*Temperature range - cap*
Dimensioni contenitore (mm)	Ø 58 X 72	*Dimensions - container (mm)*
Dimensione tappo (mm)	Ø 61 X 13	*Dimensions – cap (mm)*
Peso contenitore (gr.)	9,0	*Weight - container (gr.)*
Peso tappo (gr.)	5,8	*Weight – cap (gr.)*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

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DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (urina) al fine di effettuare analisi diagnostiche di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale Dispositivi Medici (CND) > W05010203 (Contenitori per raccolta di urina).
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1897926/R
Codice EDMA > 51021002 - Sterile urine containers

Intended purpose is "IN VITRO MEDICAL DEVICE" adapted to contain a human biological sample (urine) in order to perform diagnostic analysis laboratory. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > *W05010203 (Urine collection, containers).*
Code EDMA > 51021002 - Sterile urine containers.

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particolar substance check the resistance / compatibility chart on our catalogue

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	250	Confezione interna (pz): *Internal packing (pcs):*	singola *individually*	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	35,5 x 55 x 45,7	Peso (Kg): *Weight (Kg):*	5,5	Volume (m^3): *Volume (m^3):*	0,089

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

Sterilizzazione con radiazioni ionizzanti
Sterilization by ionizer rays

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
25.11.2020

MADE IN ITALY

CODICE ARTICOLO: **SACCHETTI PER AUTOCLAVE IN POLIPROPILENE**
ITEM CODE: ***POLYPROPYLENE AUTOCLAVE BAGS***

DESCRIZIONE / *DESCRIPTION*

Sacchetti in polipropilene (PP), per sterilizzazione in autoclave, resistenti fino a 134°C. Sacchetto tipo "monopiega".
Questi sacchetti sono particolarmente utili per eliminare, mediante sterilizzazione in autoclave, sostanze patogene presenti in recipienti contaminati (pipette, provette, piastre Microtiter, ecc.).
Simbolo "BIOHAZARD" ed istruzioni per l'uso stampate direttamente sul sacchetto.
Spessore 40 my.

Polypropylene (PP) bags for autoclave sterilization, resistant up to 134°C. Bags single fold type.
These bags are particularly useful in order to remove, by autoclave sterilization process, pathogenic substances normally present in contaminated containers (pipettes, test tubes, Microtiter plates, ecc.).
"BIOHAZARD" symbol and operating instructions directly printed on the bag.
Thickness 65 my

SIMBOLO "BIOHAZARD" ED ISTRUZIONI PER L'USO STAMPATE DIRETTAMENTE SUL SACCHETTO.
STAMPA MONOCOLORE GIALLA CONFORME ALLA UNI 7545/1-10 (PANTONE 109C / RAL 1023) SU SACCHETTO TRASPARENTE.

"BIOHAZARD" SYMBOL AND OPERATING INSTRUCTIONS DIRECTLY PRINTED ON THE BAG. WRITTEN IN YELLOW COLOUR CONFORM TO UNI 7545/1-10 (PANTONE 109C / RAL 1023) PRINTED ON TRANSPARENT BAG.

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CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbiological status*
Materiale impiegato	POLIPROPILENE / *POLYPROPYLENE*	*Raw material*
Temperatura massima di utilizzo	+ 134 °C (+273.2 °F)	*Max working temperature*
Spessore	40 MY	*Thickness*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

CODICE *CODE*	DIMENSIONI (MM) *DIMENSIONS (MM)*	SPESSORE (MY) *THICKNESS (MY)*	VOLUME (L) *VOLUME (L)*	QUANTITÀ PER CONFEZIONE *QUANTITY FOR BOX*	DIMENSIONE DELLA CONFEZIONE *BOX DIMENSIONS*
10570	300 x 660	40	about 15	1.000	460 x 360 x 250 mm Vol. 0,041 m^3 15,0 Kg.
10571	400 x 660	40	about 30	1.000	460 x 360 x 250 mm Vol. 0,041 m^3 20,0 Kg.
10572	600 x 760	40	about 80	500	460 x 360 x 250 mm Vol. 0,041 m^3 16,5 Kg.
Tolleranze dimensionali / *Dimensional tollerances:* ± 5 mm					

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella per "USI GENERALI DI LABORATORIO". Prodotto adatto per effettuare la sterilizzazione in autoclave.
IL PRODOTTO NON È SOGGETTO A MARCATURA CE
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale in laboratori di analisi.

Intended purpose: "GENERAL LABORATORY USE". Product suitable for autoclave sterilization.
PRODUCT NOT SUBJECT TO CE MARKING.
For use in professional test laboratory only

RACCOMANDAZIONI PER L'USO

> I contenitori riempiti con liquido non devono essere sigillati o tappati;
> Non introdurre oggetti appuntiti, come vetreria rotta, nei sacchi per autoclave;
> Aggiungere un po' d'acqua ai sacchi contenenti residui solidi. L'acqua vaporizzerà convogliando all'esterno l'aria residua una volta raggiunta la temperatura di sterilizzazione internamente ai sacchi;
> Non chiudere il sacco, in quanto ciò impedirà all'aria di allontanarsi durante il processo di sterilizzazione;
> Non sovraccaricare l'autoclave e lasciare uno spazio sufficiente alla circolazione del vapore;
> Per la decontaminazione ed inertizzazione di rifiuti biologici particolarmente resistenti, autoclavare a +134°C

> Containers filled with liquid, must not be sealed or tapped;
> Do not introduce sharp objects, such as broken glassware, into the autoclave bags;
> Add a little high of water into the bags containing solid residues. The water will vaporize channeling outside the residual air once reached the sterilization temperature internally to the bags;
> Do not close the bag as this will avoid to the air to move out during the sterilization process;
> Do not overload the autoclave and leave enough space for the steam circulation;
> For the decontamination and deactivation of biological waste, particularly resistant, to do autoclave process at +134 °C.

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AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substances, check the resistance / compatibility chart on our catalogue

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

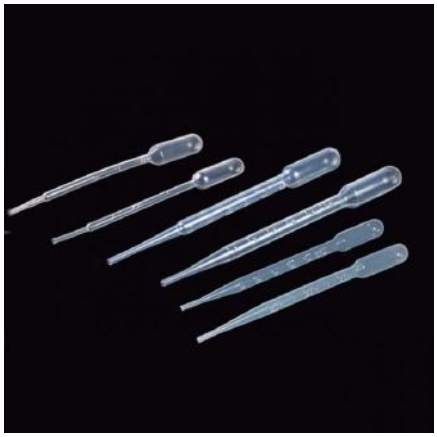
PARAFILM® ROLLS AND CUTTER

Sealing film for laboratory containers. Suitable for any container, it has stretching power of 200% and can adhere on angles or irregular surface. The cutter is planned to safety store and cut Parafilm® sealing film. It can accomodate rolls of 50 and 100 mm widh.

Cod.	Description	Dim. (mm x m)
10901	Parafilm® roll	100 x 38
10902	Parafilm® roll	50 x 75

Pasteur Pipette

LDPE Pasteur Pipette



BOENMED manufactures LDPE PASTEUR PIPETTE. The Pasteur Pipette is suitable for drawing, transferring and blending various volumes of liquid.
The pasteur pipette is made from medical grade LDPE-a safe and convenient alternative to glass pipettes.
Graduated pasteur pipette,with moulded graduations make it easy to perform quick measured liquid transfer.
Transfer pipette,with variety of volume for choices. 1ml,,3ml,5ml.
Available for E.O. sterilization or non sterile.
Bulk and individual packing or other.

Application
The LDPE Pasteur Pipettes are suitable for chemistry pH meter maintenance, laboratory tests, diagnostic test kits, slide tests, extracting samples, and adding reagents/chemicals.

Cat No.	Description	Qty/Case
640702	**Pasteur pipette 1ml, with graduation, sterile, individual pack**	**30000**
640703	Pasteur pipette 3ml, with graduation, bulk pack	20000
640704	**Pasteur pipette 3ml, with graduation, sterile, individual pack**	20000

plastic pasteur pipettes manufacturers, disposable plastic pasteur pipettes suppliers, plastic pasteur pipettes, polyethylene plastic pasteur pipettes, disposable plastic pasteur pipettes, plastic pasteur pipettes suppliers, china disposable plastic pasteur pipettes, disposable plastic pasteur pipettes manufacturers, pasteur pipettes, pasteur pipettes factory, sterile pasteur pipettes, disposable pasteur pipettes, pipettes pasteur, sterile pasteur pipettes factory, pasteur pipettes plastic, pasteur transfer pipettes

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SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
06.11.2020

MADE IN ITALY

ARTICOLO: **SACCHETTI PER STOMACHER®**
ITEM: ***BAGS FOR STOMACHER®***

DESCRIZIONE / *DESCRIPTION*

Sacchetti sterili per omogeneizzatori a battuta tipo Stomacher®
Sacchetti trasparenti,sterili R, con sigillo a strappo. Infatti per aprirli è necessario strappare lungo la linea tratteggiata posta sulla parte superiore. In tal modo l'operatore ha la certezza che il sacchetto sia sterile anche se la confezione è stata in precedenza aperta. I sacchetti sono testati in base a diversi parametri, in particolare capacità di apertura, tenuta alla base e dimensioni. I sacchetti per Stomacher® 400 sono disponibili anche nella versione con fondo interno arrotondato tipo "circulator" e rinforzato per migliorare la circolazione del campione, evitando il ristagno negli angoli. I sacchetti prodotti in LDPE hanno uno spessore di 65 µm. I sacchetti prodotti in PA/PE (Nylon) hanno uno spessore di 70 µm, ideali per sostanze particolarmente dure e per tempi di omogeneizzazione più lunghi. Sacchetti conformi per alimenti secondo la legislazione vigente. Disponibili anche nella versione "Closure bag" sigillabile tramite bioadesivo che consente l'utilizzo dello stesso sacchetto sia per il campionamento sia per l'omogeneizzazione. Dispositivi Latex Free

Sterile bags for Stomacher® blenders
Transparent bags, sterile R, with tear seal. In fact, is necessary for opening tear along the dotted line on the top. In this way the operator has the assurance that the bag is sterile, even if the package has been previously opened. Bags are tested by various parameters, in detail by opening capacity, sealing at the base and dimensions. Bags for Stomacher® 400 are also available with rounded inner bottom "circulator" type and strengthened to improve the circulation of the sample, avoiding the stagnation in the corners. Bags made in LDPE have a thickness of 65 µm. Bags made in PA/PE (nylon) have a thickness of 70 µm, ideal for particularly hard substances and for more long blending time. Suitable for foodstuff in accordance with applicable law. Available also in "Closure bag" version sealable by double sided tape that allows the use of the same bag, both for sampling and blanding. Latex free device.

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella per "USI GENERALI DI LABORATORIO". Sacchetti ideali per la raccolta, la macinazione e l'omogeneizzazione dei prodotti alimentari o similari. Prodotto non soggetto a marcatura CE.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.

Intended purpose: "GENERAL LABORATORY USE". Ideal for sampling, mincing and homogenisation of foodstuff or similar.
PRODUCT NOT SUBJECT TO CE MARKING.
For professional use only.

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Sacchetti per Stomacher® 80 / *Bags for Stomacher® 80*

Compatibilità	***Compatibility***
Stomacher® 80 & 80 MicroBiomaster (o similari / *or similar*)	
Stato microbiologico	***Microbilogical status***
Sterile tramite radiazioni ionizzanti Raggi Beta 21 kGy *Sterile by ionizer Beta Rays 21 kGy*	
Materiale	***Raw material***
Polietilene bassa densità (LDPE) / *Low Density Polyethylene (LDPE)*	
Dimensioni	***Dimensions***
105 x 155 mm	
VOLUME	***VOLUME***
5 - 80 ml	
SPESSORE	***THICKNESS***
65 µm	
COD. 10301	
Tipo fondo	*Bottom type*
Quadrato / *Square*	
Tipo chiusura	*Closure type*
Standard	
COD. 10302	
Tipo fondo	***Bottom type***
Quadrato / *Square*	
Tipo chiusura	***Closure type***
"Closure bag" sigillabile tramite biadesivo *"Closure bag" version sealable by double sided tape*	

Sacchetti per Stomacher® 3500 / *Bags for Stomacher® 3500*

Compatibilità	***Compatibility***
Stomacher® 3500 Jumbo (o similari / *or similar*)	
Stato microbiologico	***Microbilogical status***
Sterile tramite radiazioni ionizzanti Raggi Beta 21 kGy *Sterile by ionizer Beta Rays 21 kGy*	
Materiale	***Raw material***
Polietilene bassa densità (LDPE) / *Low Density Polyethylene (LDPE)*	
Dimensioni	***Dimensions***
380 x 510 mm	
VOLUME	***VOLUME***
400 - 3500 ml	
SPESSORE	***THICKNESS***
65 µm	
COD. 10321	
Tipo fondo	***Bottom type***
Quadrato / *Square*	
Tipo chiusura	***Closure type***
Standard	

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Sacchetti per Stomacher® 400 / *Bags for Stomacher® 400*

Stato microbiologico	***Microbilogical status***
Sterile tramite radiazioni ionizzanti Raggi Beta 21 kGy *Sterile by ionizer Beta Rays 21 kGy*	
Dimensioni	***Dimensions***
180 x 320 mm	
VOLUME	***VOLUME***
80 - 400 ml	
COD. 10310	
Compatibilità	***Compatibility***
Stomacher® 400 Classic (o similari / *or similar*)	
Materiale	***Raw material***
Polietilene bassa densità (LDPE) / *Low Density Polyethylene (LDPE)*	
SPESSORE	***THICKNESS***
65 µm	
Tipo fondo	***Bottom type***
Quadrato / *Square*	
Tipo chiusura	***Closure type***
Standard	
COD. 10311	
Compatibilità	***Compatibility***
Stomacher® 400 Classic (o similari / *or similar*)	
Materiale	***Raw material***
Polietilene bassa densità (LDPE) / *Low Density Polyethylene (LDPE)*	
SPESSORE	***THICKNESS***
65 µm	
Tipo fondo	***Bottom type***
Quadrato / *Square*	
Tipo chiusura	***Closure type***
"Closure bag" sigillabile tramite biadesivo *"Closure bag" version sealable by double sided tape*	
COD. 10312	
Compatibilità	***Compatibility***
Stomacher® 400 Circulator (o similari / *or similar*)	
Materiale	***Raw material***
PA / PE (Nylon)	
SPESSORE	***THICKNESS***
70 µm	
Tipo fondo	***Bottom type***
Circulator	
Tipo chiusura	***Closure type***
Standard	
COD. 10313	
Compatibilità	***Compatibility***
Stomacher® 400 Circulator (o similari / *or similar*)	
Materiale	***Raw material***
PA / PE (Nylon)	
SPESSORE	***THICKNESS***
70 µm	
Tipo fondo	***Bottom type***
Circulator	
Tipo chiusura	***Closure type***
"Closure bag" sigillabile tramite biadesivo *"Closure bag" version sealable by double sided tape*	

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CONFEZIONE / *PACKAGING*

Codice *Code*	Quantità *Quantity*	Dimensioni (cm) *Dimensions (cm)*	Volume (m^3) *Volume (m^3)*	Peso (Kg.) *Weight (Kg.)*
10301	10 x 100 pcs	35,5 x 23,5 x 25,5	0,021	2,5
10302	10 x 100 pcs	35,5 x 23,5 x 25,5	0,021	2,5
10310	10 x 100 pcs	35 x 22,6 x 18,5	0,015	8,85
10311	10 x 100 pcs	35 x 22,6 x 18,5	0,015	9
10312	10 x 100 pcs	35,5 x 23,5 x 25,5	0,021	10
10313	10 x 100 pcs	35,5 x 23,5 x 25,5	0,021	10
10321	20 x 50 pcs	46 x 36 x 25	0,041	24

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substances, check the resistance / compatibility chart on our catalogue

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS

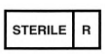

Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable



Sterilizzazione con radiazioni ionizzanti
Sterilization by ionizer rays

ВИНАР®
НАУЧНО-ПРОИЗВОДСТВЕННАЯ ФИРМА

«УТВЕРЖДАЮ»
Генеральный директор
ООО «НПФ «ВИНАР»
В.С.Андреев
20 марта 2019 г.

Регистрационные удостоверения № ФСР 2009/04944 от 27.08.2019 г., № ФСР 2009/05017 от 27.08.2019 г.

ИНСТРУКЦИЯ
по применению индикаторов химических одноразовых воздушной стерилизации МедИС-В №154.098.03 ИП

Настоящая инструкция распространяется на индикаторы химические одноразовые воздушной стерилизации МедИС-В (далее – «индикаторы»), выпускаемые в соответствии с ТУ 9398-032-11764404-2004 в следующих исполнениях: **МедИС-В-160/150, МедИС-В-180/60.**

1. НАЗНАЧЕНИЕ

Индикаторы предназначены для оперативного визуального контроля соблюдения критических переменных воздушной стерилизации – температуры и времени стерилизационной выдержки – **в камере воздушных стерилизаторов по ГОСТ 22649-83.**

Применение индикаторов позволяет обнаружить несоблюдение режима стерилизации, обусловленное технической неисправностью стерилизаторов, нарушением правил их загрузки, ошибкой в установке параметров или их сбоем, и тем самым исключить возможность использования нестерильных медицинских изделий.

Индикаторы обеспечивают документированное подтверждение контроля параметров стерилизации с сохранностью результатов в качестве документа архива в течение не менее 12 месяцев.

Индикаторы предназначены для использования персоналом учреждений, предприятий и служб, эксплуатирующих и контролирующих стерилизационное оборудование.

2. ОСНОВНЫЕ ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ

Индикаторы соответствуют классу 4 (многопеременные индикаторы) по классификации ГОСТ ISO 11140-1-2011.

Индикатор представляет собой полоску прямоугольной формы из инертного бумажного основания с нанесёнными на лицевой стороне двумя цветовыми метками: индикаторной меткой и элементом сравнения. Так же на лицевую сторону нанесена маркировка, включающая: товарный знак или наименование предприятия-производителя; обозначение «ВОЗД» контролируемого воздушного метода стерилизации; класс индикатора по ГОСТ ISO 11140-1-2011 (класс 4); обозначение контролируемого режима стерилизации – температуры и времени выдержки.

Цвет индикаторной метки необратимо меняется в зависимости от достигнутых значений критических переменных в течение цикла воздушной стерилизации. Элемент сравнения показывает конечный цвет индикаторной метки при соблюдении требуемых условий стерилизации.

На обратной стороне индикатора нанесен липкий слой, закрытый двумя половинками защитной бумаги, служащий для его фиксации в месте контроля и в качестве документа архива.

Индикатор не оставляет следов на материалах, с которыми соприкасается до, в процессе и после стерилизации.

Индикаторы поставляются в листах с перфорацией между индикаторами.

Режимы стерилизации (условия в камере стерилизатора), для контроля которых предназначены индикаторы, и соответствующие им контрольные значения индикаторов приведены в таблице 1.

Таблица 1 – Режимы стерилизации и соответствующие им контрольные значения индикаторов

Наименование индикатора	Режим воздушной стерилизации (условия в камере стерилизатора)		Контрольные значения индикатора	
	Температура стерилизации, °С	Время стерилизационной выдержки, мин	Температура, °С	Время выдержки, мин
МедИС-В-160/150	160±3	150^{+5}	160	150
МедИС-В-180/60	180±3	60^{+5}	180	60

3. ПРОТИВОПОКАЗАНИЯ К ПРИМЕНЕНИЮ

Индикаторы запрещается использовать в режимах стерилизации, не указанных на индикаторах и в инструкции. Использование индикаторов в нерегламентированных режимах приводит к ложным результатам контроля. Не допускается размещать индикаторы МедИС-В внутри стерилизуемых изделий и упаковок. Для контроля условий стерилизации внутри изделий и упаковок необходимо использовать индикаторы СТЕРИТЕСТ-В, СТЕРИТЕСТ-Вл.

4. ПОДГОТОВКА ИНДИКАТОРОВ К ИСПОЛЬЗОВАНИЮ

Перед использованием индикаторов вскрыть потребительскую упаковку, достать индикаторные листы, внимательно изучить инструкцию по применению и маркировку индикаторов.

ВНИМАНИЕ! Перед стерилизацией медицинские изделия необходимо высушить в сушильном шкафу при t=85°С до исчезновения видимой влаги.

5. ПОРЯДОК ПРИМЕНЕНИЯ ИНДИКАТОРОВ

Все операции с индикаторами – их размещение в камере стерилизатора, выемку, интерпретацию результатов и документирование – осуществляет персонал, проводящий стерилизацию.

Индикаторы обязательны к применению в каждом цикле стерилизации. Количество индикаторов, закладываемых в стерилизатор, зависит от объема камеры стерилизатора (таблица 2, рис.1).

От листа с индикаторами по линии перфорации отделить необходимое количество индикаторов (табл.2) и пронумеровать их в соответствии с нумерацией контрольных точек (рис.1). Индикаторы поместить в камере стерилизатора с внешней стороны упаковок и контейнеров со стерилизуемыми изделиями, придерживаясь расположения контрольных точек (рис.1). В каждую точку помещать не менее одного индикатора.

Для закрепления индикатора с его обратной стороны удалить часть защитного бумажного покрытия, закрывающего липкий слой со стороны

логотипа “ВИНАР” по линии надсечки и приклеить индикатор с освободившимся липким слоем к внешней стороне упаковок и на бирки стерилизационных коробок (биксов) с медицинскими изделиями, по возможности придерживаясь расположения контрольных точек (рис.1).

Закрепление индикаторов производить:

- при использовании бумажных пакетов – на заклеивающийся клапан пакета;
- при использовании листовых бумажных оберточных материалов – на оставшийся свободным после заворачивания угол бумаги;
- при использовании стерилизационных контейнеров – на бирку контейнера.

Таблица 2 – Количество индикаторов, закладываемых в стерилизатор, в зависимости от объема камеры стерилизатора

Объём камеры воздушного стерилизатора, дм^3	Количество контрольных точек
До 80 включительно	5
Свыше 80 однокамерные	15
Свыше 80 двухкамерные	30 (по 15 в каждой камере)

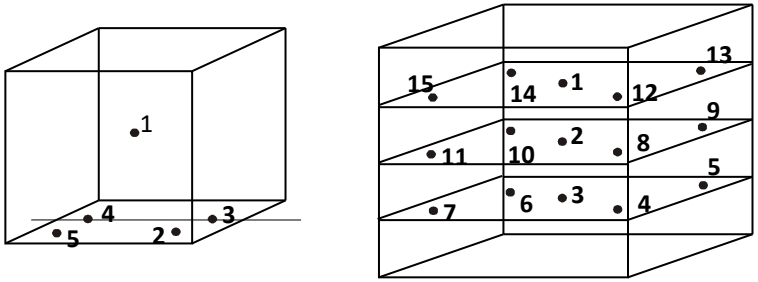


Рис.1 - Расположение контрольных точек в воздушных стерилизаторах

ПРИМЕЧАНИЕ: *в воздушных стерилизаторах индикаторы помещать на расстоянии не менее 5 см от стенок стерилизационной камеры.*

ВНИМАНИЕ! Запрещается закреплять индикаторы индикаторной меткой к поверхности упаковки и стерилизационного контейнера, а также закреплять на стенках и двери (крышке) стерилизационной камеры.

По окончании цикла стерилизации не приклеенную часть индикатора с цветовыми метками оторвать по линии перфорации от приклеенной части и оценить изменение цвета индикаторной метки каждого индикатора.

ВНИМАНИЕ! Запрещается отделять липкий слой индикаторов от упаковки из бумаги во избежание нарушения целостности упаковки и контаминации её содержимого.

При соблюдении параметров воздушной стерилизации индикаторная метка должна приобретать коричневый цвет, в соответствии с цветом элемента сравнения, или быть светлее, или темнее него.

Если после проведения режима стерилизации индикаторная метка хотя бы одного индикатора имеет цвет с зеленым оттенком, легко отличимый от цвета элемента сравнения, требуемые значения критических переменных в камере стерилизатора не были соблюдены, все изделия загрузки считаются нестерильными и подлежат повторной стерилизации после устранения причин неудовлетворительных результатов контроля.

ПРИМЕЧАНИЯ:

1. Оттенки цвета элемента сравнения индикаторов разных партий могут иметь незначительные различия в пределах погрешности цветопередачи при изготовлении индикаторов.
2. В зависимости от особенностей освещения (освещенность, естественное или искусственное, тип ламп и др.) конечный цвет индикаторной метки может иметь различные оттенки.
3. В зависимости от типа стерилизатора, плотности загрузки, режима стерилизации конечный цвет индикаторной метки может быть как светлее, так и темнее элемента сравнения.
4. Допускается светлый ореол вокруг индикаторной метки после стерилизации.

6. РЕМОНТ И ТЕХНИЧЕСКОЕ ОБСЛУЖИВАНИЕ

Индикаторы предназначены для однократного применения и не подлежат ремонту и техническому обслуживанию.

7. ПРАВИЛА ХРАНЕНИЯ, ДОКУМЕНТИРОВАНИЯ И УТИЛИЗАЦИИ

На потребительской упаковке индикатора указаны: сведения об однократности применения (символ «одноразовое использование» по ГОСТ Р ИСО 15223-1-2020); товарный знак или наименование предприятия-производителя; юридический адрес и адрес для писем производителя; наименование индикаторов; количество индикаторов в комплекте и наличие журнала; дата изготовления индикаторов; обозначение технических условий; класс индикаторов по ГОСТ ISO 11140-1-2011 (класс 4), условия хранения индикаторов; номер и дата выдачи Регистрационного удостоверения Росздравнадзора; гарантийный срок годности; штамп ОТК; номер партии изделия по системе нумерации предприятия-производителя.

Хранить индикаторы следует в упаковке изготовителя при температуре от плюс 5 °С до плюс 40 °С и относительной влажности не выше 80% при +25 °С, в защищённом от солнечного света месте. Избегать попадания влаги и прямых солнечных лучей на упаковку и индикаторную метку.

Гарантийный срок годности при соблюдении условий хранения составляет 36 месяцев.

Документирование результатов химического контроля стерилизации следует производить в «Журнал контроля работы стерилизаторов…» (форма 257/у) с записью в соответствующие графы информации по каждому циклу стерилизации. Индикаторы, подтверждающие результаты контроля, подклеиваются с помощью нанесенного на них липкого слоя в соответствующий столбец химического контроля и хранятся в качестве документа архива не менее 12 месяцев.

Индикаторы, в том числе использованные, не оказывают вредного воздействия на человека и окружающую среду, не требуют соблюдения особых мер безопасности и могут утилизироваться как безопасные медицинские отходы класса А.

Производитель: ООО «НПФ «ВИНАР»
(Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»)
105094, Россия, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
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+7 (800) 201 0202, +7 (495) 988 7667 www.vinar.ru

GIMA STD DISPOSABLE SCALPELS N. 23 - sterile

Code:	**27067**
Category:	**PARAGON, SWANN MORTON and GIMA branded scalpels and scalpel blades**
Unit of sale:	**box of 10 pcs.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**2382102**
CND:	**V010102**
EAN13:	**8023279270679**

Description: **"GIMA" DISPOSABLE SCALPELS - sterile - STANDARD MODEL**

S/S blade fitted into an ABS plastic handle. Individually packed in sterilized envelope.

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DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede operativa in Gessate (MI), in Via Marconi 1, e sede legale in Milano, in Via Tommaso Grossi 2, in qualità di fabbricante del dispositivo medico:
We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Dispositivo medico / *Medical Device*	**Codice/Code**
FORBICI MAYO STILLE - rette - 18 cm *MAYO STILLE SCISSORS straight - 18 cm*	26847

Classe di rischio I (Non Sterile), in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tale dispositivo:
Risk class I (Not Sterile), according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declares, under its own responsibility, that this medical device:

- è conforme ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- è fabbricato in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  is manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 4/1/2020

GIMA S.p.A.
Il legale Rappresentante
The legal Representative
(Nicola Manzoni)

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	GIMA SPA
Manufacturer address and contact details	Via Tommaso Grossi, 2 20121 Milano – Italy Email: regolatorio@gimaitaly.com Telephone number: +39 029538541 Website: www.gimaitaly.com
Single Registration Number (SRN) (if available)	IT-MF-000011004

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	ICIM SPA □ See attached schedule
Notified body number (if applicable)	0425 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Capital € 364.000,00 V.A.T. (IVA) Registration No. IT 00734640154 - Registered in Italy: R.E.A. Mi 477226
Reg. Imp. Tribunale di Milano 00734640154 - Registered Office: Via Tommaso Grossi, 2 – 20121 Milano

Directive Certificate number(s) to which this confirmation is made (if applicable)	
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

□ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

□ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

X A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name: GIMA SPA

Location & Date: Gessate 20.03.2025

Signature, Print Name, Title Nicola Manzoni, Legal Representative

Contact Details (at least email): regolatorio@gimaitaly.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Reusable surgical instruments	-	-	-	ICIM SPA n. 0425	2028-12-31	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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MAYO STILLE SCISSORS straight - 18 cm

Code:	**26847**
Category:	**Scissors**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**149530**
CND:	**L010499**
EAN13:	**8023279268478**

Description: **STAINLESS STEEL MAYO-STILLE SURGICAL SCISSORS.**

Instructions: GB, FR, IT, ES, PT, DE, GR, Arabic.

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DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede operativa in Gessate (MI), in Via Marconi 1, e sede legale in Milano, in Via Tommaso Grossi 2, in qualità di fabbricante del dispositivo medico:
We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Dispositivo medico / *Medical Device*	**Codice/Code**
PINZA CHIRURGICA - 16 cm, 1x2 denti *SURGERY FORCEPS - 16 cm 1x2*	26693

Classe di rischio I (Non Sterile), in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tale dispositivo:
Risk class I (Not Sterile), according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declares, under its own responsibility, that this medical device:

- è conforme ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- è fabbricato in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  is manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 4/1/2020

GIMA S.p.A.
Il legale Rappresentante
The legal Representative
(Nicola Manzoni)

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	GIMA SPA
Manufacturer address and contact details	Via Tommaso Grossi, 2 20121 Milano – Italy Email: regolatorio@gimaitaly.com Telephone number: +39 029538541 Website: www.gimaitaly.com
Single Registration Number (SRN) (if available)	IT-MF-000011004

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	ICIM SPA □ See attached schedule
Notified body number (if applicable)	0425 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Reg. Imp. Tribunale di Milano 00734640154 - Registered Office: Via Tommaso Grossi, 2 – 20121 Milano

Directive Certificate number(s) to which this confirmation is made (if applicable)	
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

□ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

□ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

X A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name: GIMA SPA

Location & Date: Gessate 20.03.2025

Signature, Print Name, Title Nicola Manzoni, Legal Representative

Contact Details (at least email): regolatorio@gimaitaly.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Reusable surgical instruments	-	-	-	ICIM SPA n. 0425	2028-12-31	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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SURGERY FORCEPS - 16 cm 1x2

Code:	**26693**
Category:	**Forceps**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**141832**
CND:	**L031310**
EAN13:	**8023279266931**
Description:	**Stainless Steel surgery forceps - 16 cm 1 x 2**

Палочка стеклянная, длина 220 мм, МиниМед,

Артикул: 12005601

Палочка стеклянная, длина 220 мм, МиниМед, уп.100/600 шт

Описание товара

Артикул..... 12005601

Длина..... 220 ± 5,0 мм

Диаметр..... 5 ± 0,5 мм

Упаковка..... 100 шт.

Предназначена для перемешивания невязких растворов. Изготовлена из стекла ТС по ГОСТ 21400-75.

Изготовлена по ТУ 4320-012-29508133-2009.