

ELITE InGenius



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NOTICE of CHANGE dated 05/05/2022

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«ELITE InGenius® Sonication tubes» Ref. INT032SON

This new revision of the Instruction for Use (IFU) contains the following changes:

- *Update to be in compliance with the Regulation (EU) 2017/746 and the Standard ISO 15223-1:2021 requirements.*

Use and performance of the product remain unchanged.

PLEASE NOTE



LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT



THE REVIEW OF THIS IFU IS ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT



CET IFU MIS A JOUR ANNULE ET REMPLACE ET EST PARFAITEMENT COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT



LA REVISIÓN DE ESTE IFU ES COMPATIBLE TAMBIÉN CON LA VERSIÓN ANTERIOR DEL KIT



A REVISÃO DO ESTE IFU ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT



DIE REVIEW VON DIESER IFU IST KOMPATIBLE MIT DER VORIGE VERSION VON DEM TEST-KIT

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ELITechGroup
EMPOWERING IVD



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ELITE InGenius® Sonication tubes

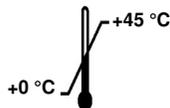
Consumables for sonication process

REF INT032SON



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TABLE OF CONTENTS

INTENDED USE	page 1
DESCRIPTION	page 1
MATERIALS PROVIDED	page 2
MATERIALS REQUIRED BUT NOT PROVIDED	page 2
OTHER PRODUCTS REQUIRED	page 2
WARNINGS AND PRECAUTIONS	page 2
PROCEDURE	page 3
SYMBOLS	page 4
NOTICE TO PURCHASER: LIMITED LICENSE	page 4

INTENDED USE

The product «ELITE InGenius® Sonication tubes» (ELITechGroup S.p.A., code INT032SON) provides consumables for sample sonication in association with the ELITE InGenius® (ELITechGroup S.p.A., code INT030) instrument.

DESCRIPTION

The «ELITE InGenius® Sonication tubes» product provides consumables to be used with the product «ELITE InGenius® SP 200».

The product provides plastic consumables for **192 sonications** (16 runs x 12 samples).

ELITE InGenius Sonication tubes
consumables for the sonication process

REF INT032SON

MATERIALS PROVIDED

Component	Quantity	Description
Sonication tube	192	Disposable tube to be placed in the sonication position. It can also be used as secondary tube for loading samples.
Sonication tube cap	192	Cap used to seal sonication tube during sonication.

MATERIALS REQUIRED BUT NOT PROVIDED

- The following equipment and reagents are not provided:
- Disposable powder free gloves in nitril or similar material.
 - Laminar airflow hood.
 - Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips.

OTHER PRODUCTS REQUIRED

This product must be used in association with the product «ELITE InGenius SP 200» (ELITechGroup S.p.A., code INT032SP200) and the «ELITE InGenius» (ELITechGroup S.p.A., code INT030) instrument.

Extraction and Inhibition Internal Control is not included in this kit. When this extraction kit is used in association with an amplification ELITE MGB kit by ELITechGroup S.p.A., for the Extraction and Inhibition Internal Control, please refer to the amplification ELITE MGB kit IFU.

WARNING AND PRECAUTIONS

This product is exclusively designed for *in-vitro* use.

General warnings and precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. All materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards.

After receiving the set, check the set components for damage. If labware are damaged, contact the ELITechGroup S.p.A. Technical Services or your local distributor.

The plastic parts are for laboratory use only; they must be stored in the laboratory and are not to be used for purposes other than intended.

Wear suitable protective clothes and gloves and protect eyes and face.
Discard gloves if they get contaminated.
Never pipette solutions by mouth.
Do not eat, drink, smoke or apply cosmetic products in work areas.
Carefully wash hands after handling samples and reagents.
Dispose of leftover reagents and waste in compliance with local regulations.
Carefully read all the instructions provided in the product before running the assay.
While running the assay, follow the instructions provided with the product.
Do not use the product after the indicated expiry date.
Do not use damaged set components.
Only use the reagents provided in the product and those recommended by the manufacturer.
Do not use reagents from different batches.
Do not use reagents from other manufacturers.

Warnings and precautions for molecular biology

Molecular biology procedures, such as nucleic acid extraction, amplification and detection, require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or contamination of the samples by amplification products.

The samples must be exclusively used for this type of analysis. Samples must be handled under a laminar airflow hood. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be both DNase and RNase free, and DNA and RNA free.

PROCEDURE

The complete procedure involves DNA and RNA extraction and purification from fresh or frozen cellular and non-cellular fluid samples in association with the «**ELITE InGenius**».

The complete procedure, the performance characteristics and procedure limitations are described in detail in the instruction manual enclosed with «**ELITE InGenius SP 200**».

SYMBOLS

-  Catalogue Number
-  Temperature limits
-  Batch code
-  Use by (last day of month)
-  *in vitro* diagnostic medical device
-  Fulfilling the requirements of the Regulation IVDR (EU) 2017/746 for *in vitro* diagnostic medical device
-  Unique Device Identification
-  Do not reuse
-  Contains sufficient for "N" tests
-  Consult instructions for use
-  Contents
-  Keep away from sunlight
-  Manufacturer
-  Country of manufacture

NOTICE TO PURCHASER: LIMITED LICENSE

This product is in compliance with the Regulation IVDR (EU) 2017/746 on *in vitro* diagnostic medical devices. In-vitro diagnostic use of the product in countries where the Regulation IVDR (EU) 2017/746 is not recognized may be subjected to the fulfilment of registration procedures according to local competent authorities.