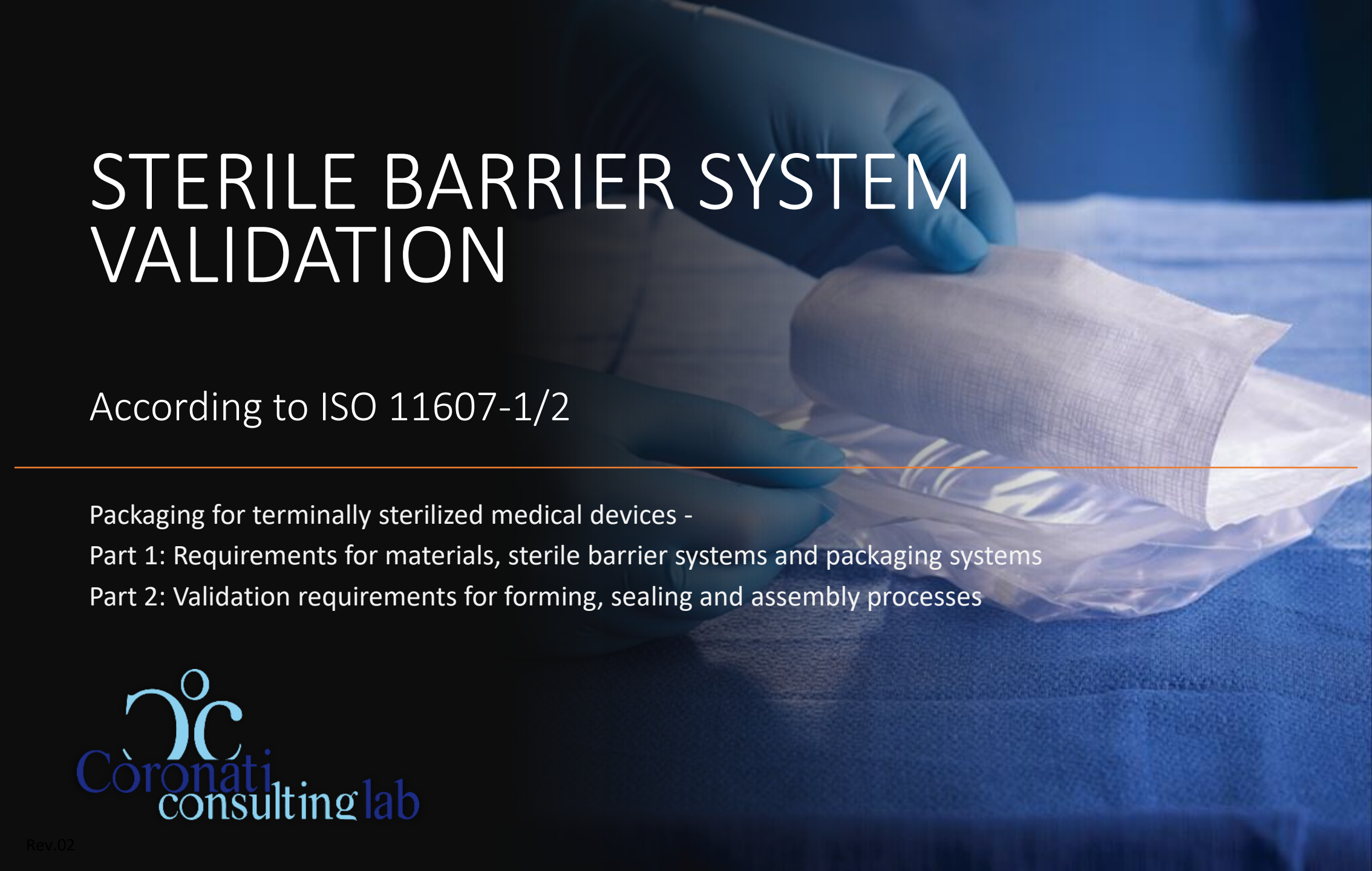

STERILE BARRIER SYSTEM VALIDATION

According to ISO 11607-1/2

Packaging for terminally sterilized medical devices -
Part 1: Requirements for materials, sterile barrier systems and packaging systems
Part 2: Validation requirements for forming, sealing and assembly processes

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Rev.02

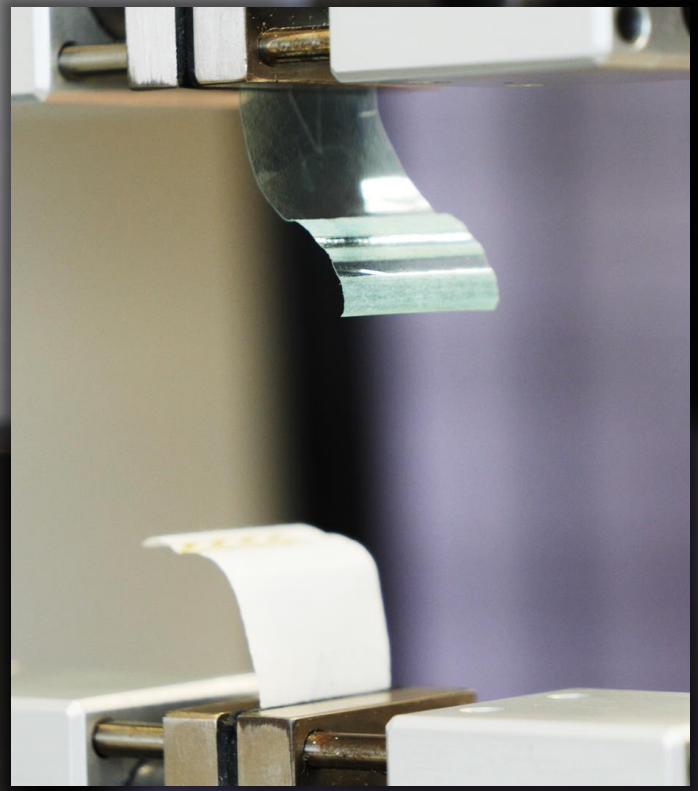
SEAL STRENGHT TEST

ISO 17025 ACCREDITED

Scope:

This test evaluates the tensile strength of specimens obtained by cutting the welds of the primary packaging of medical devices.

This evaluation is carried out using a tensile testing machine.



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SEAL STRENGHT TEST

ISO 17025 ACCREDITED

Reference Standard:

UNI EN 868-5:2019 Annex D: “Method for the determination of the strength of the seal for pouches and reel material”

ASTM F88/F88M-23

“Standard Test Method for Seal Strength of Flexible Barrier Materials”

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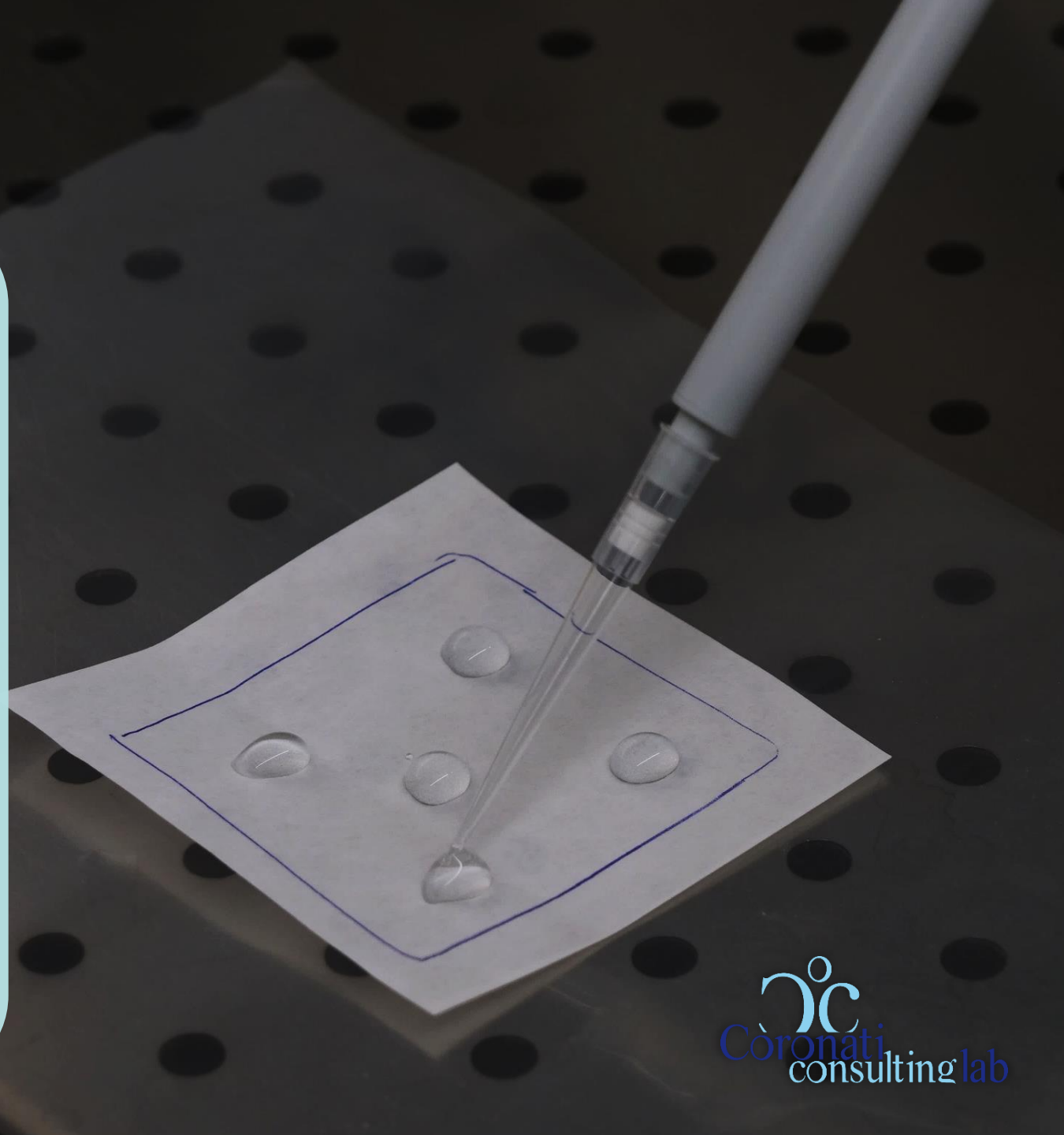
MICROBIAL BARRIER

ISO 17025 ACCREDITED

Scope:

This test consists in depositing a known quantity of microorganisms on a portion of packaging to evaluate the impenetrability to microorganisms in the presence of humidity. These procedures apply to packaging materials for medical devices intended for sterilization.



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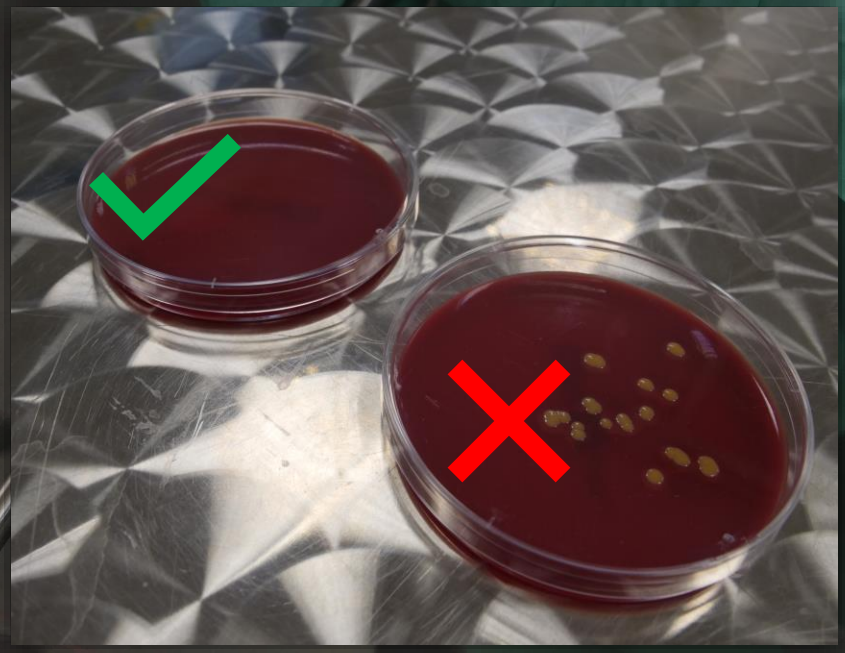
MICROBIAL BARRIER

ISO 17025 ACCREDITED

Reference Standard:

DIN 58953-6 - 2025 (section 4):

Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized.



INTACT MICROBIAL BARRIER

MICROBIAL PENETRATION

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BUBBLE TEST

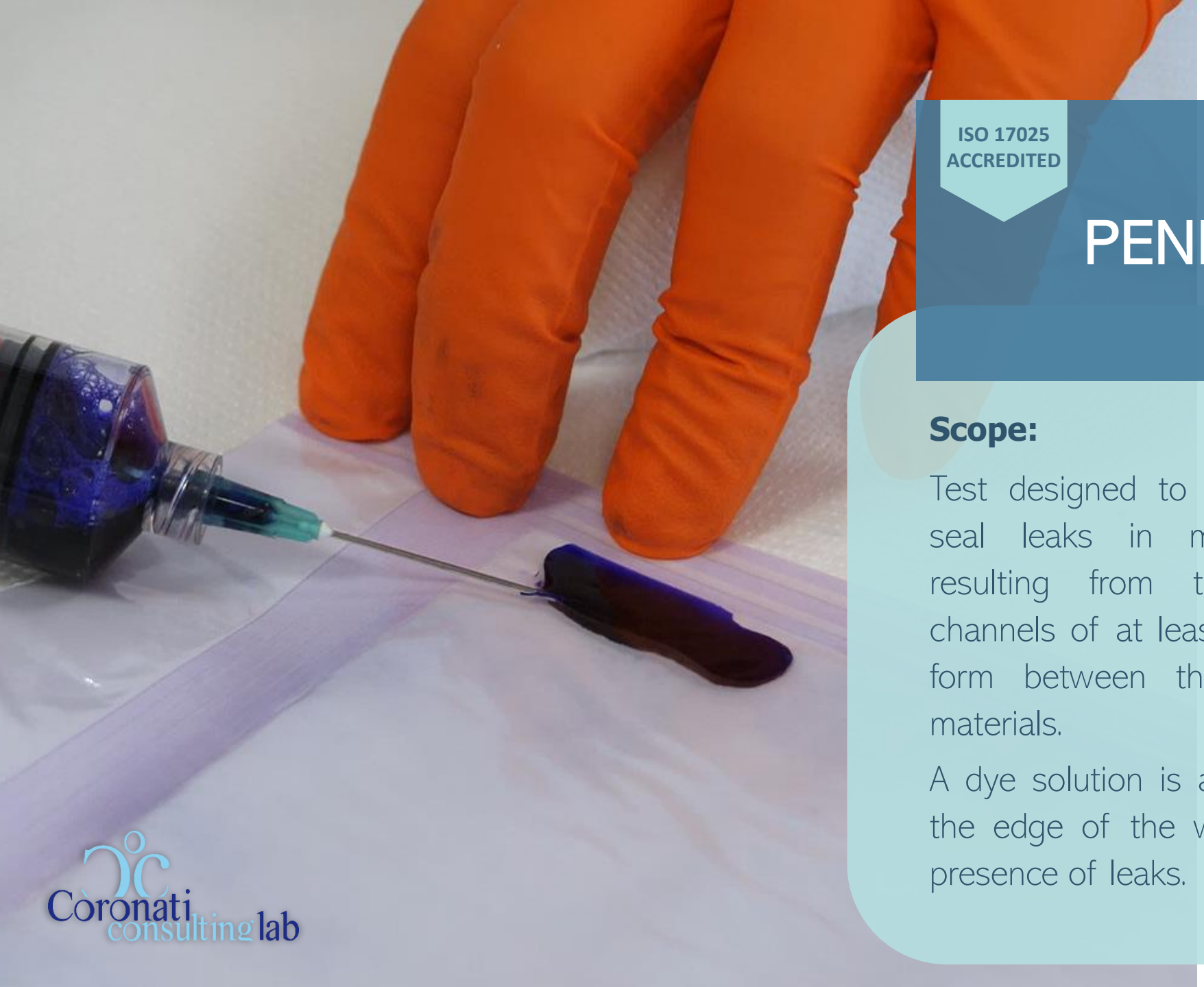
ISO 17025 ACCREDITED

Scope:

This test covers the detection of gross leaks in packaging, and it may be used for tray and pouch packages.

The package is inflated underwater to a predetermined pressure and then observed for a steady stream of air bubbles indicating a failure area.

Reference Standard:
ASTM F2096 – 11 (2019):
"Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization"



ISO 17025
ACCREDITED

DYE PENETRATION TEST

Scope:

Test designed to detect and locate seal leaks in medical packaging resulting from the presence of channels of at least 50 µm that can form between the two packaging materials.

A dye solution is applied topically to the edge of the weld to detect the presence of leaks.

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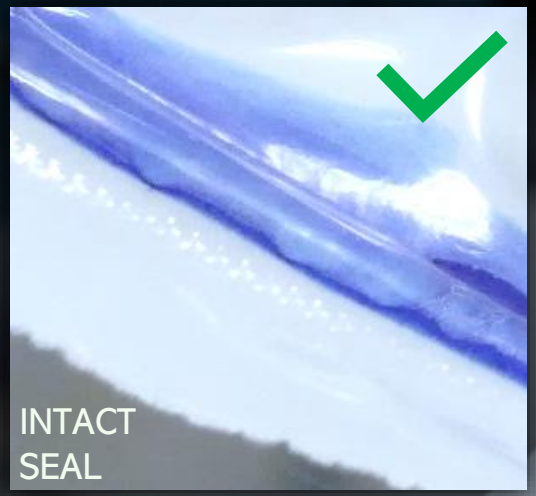

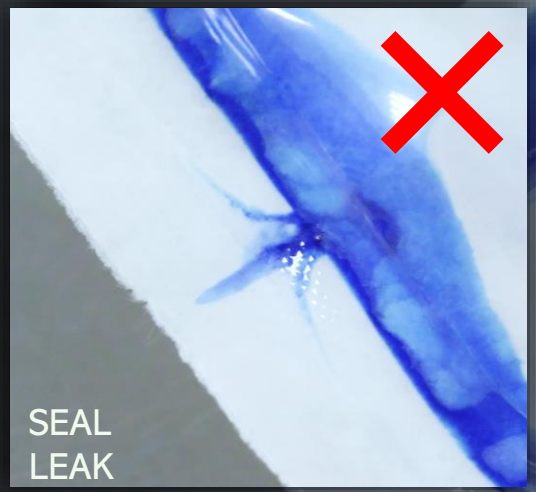

ISO 17025
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DYE PENETRATION TEST

Reference Standard:

ASTM F1929 – 23: "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"

ASTM F3039-23 method A: "Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration"

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PINHOLES TEST

ISO 17025 ACCREDITED

Scope:

Test designed to evaluate the presence or absence of micro-holes in the plastic laminate of the primary packaging of medical devices.

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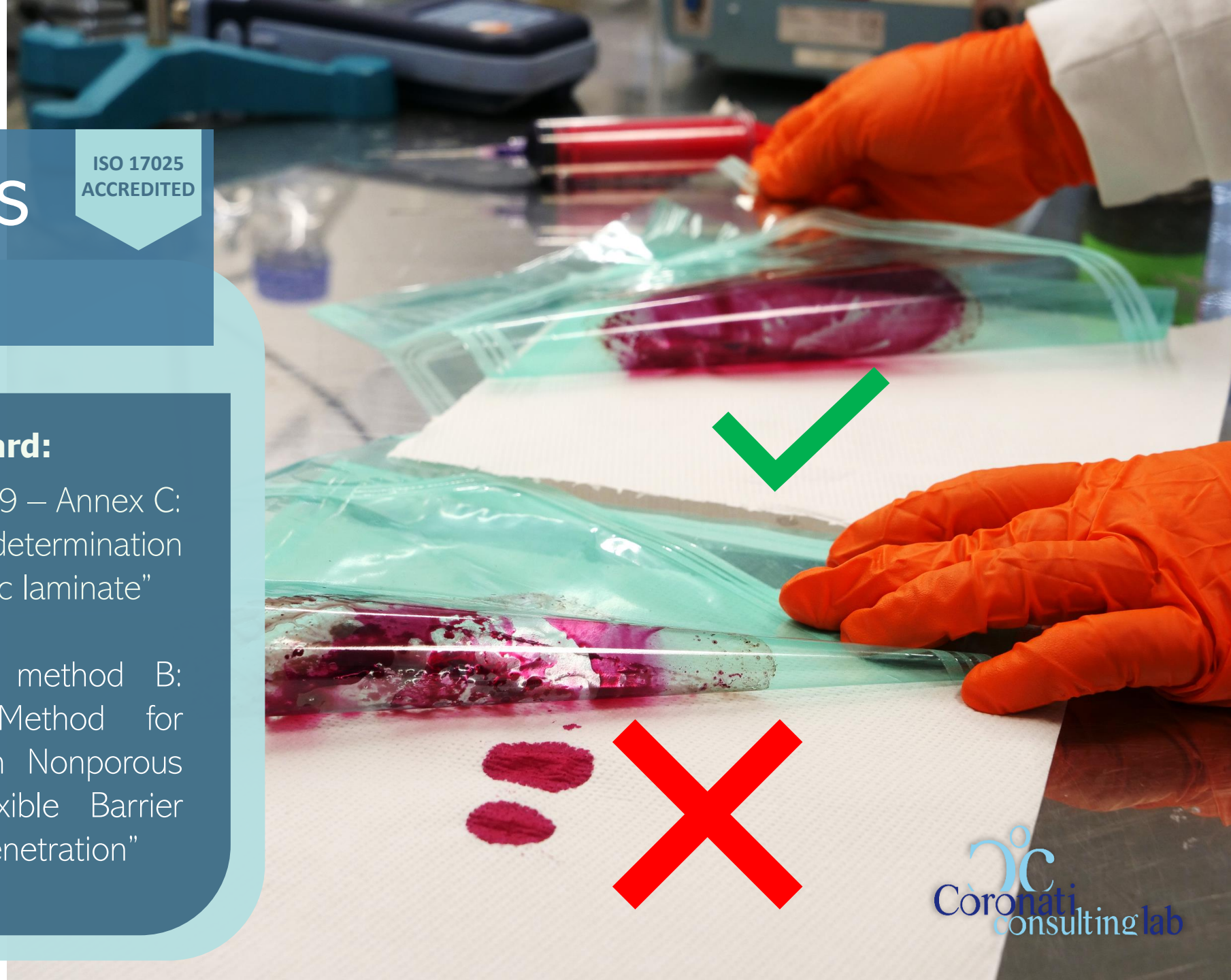
PINHOLES TEST

ISO 17025 ACCREDITED

Reference Standard:

UNI EN 868-5:2019 – Annex C: "Method for the determination of pinholes in plastic laminate"

ASTM F3039-23 method B: "Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration"



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PEEL CHARACTERISTICS TEST

ISO 17025 ACCREDITED

Scope:

Test for the evaluation of the peelability characteristics in the primary packaging of medical devices and of the width of the welds.

Reference Standard:

UNI EN 868-5:2019 Annex E:
"Method for the determination of peel characteristics
of paper/plastic laminate products"

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MEASURE OF SEALING WIDTH

ISO 17025
ACCREDITED

Scope:

Test for the evaluation of the width of the seal on the inner plastic surface in the primary packaging of medical devices.

Reference Standard:

UNI EN 868-5:2019 - Annex E:
"Method for the determination of peel characteristics of paper/plastic laminate products"

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VISUAL INSPECTION

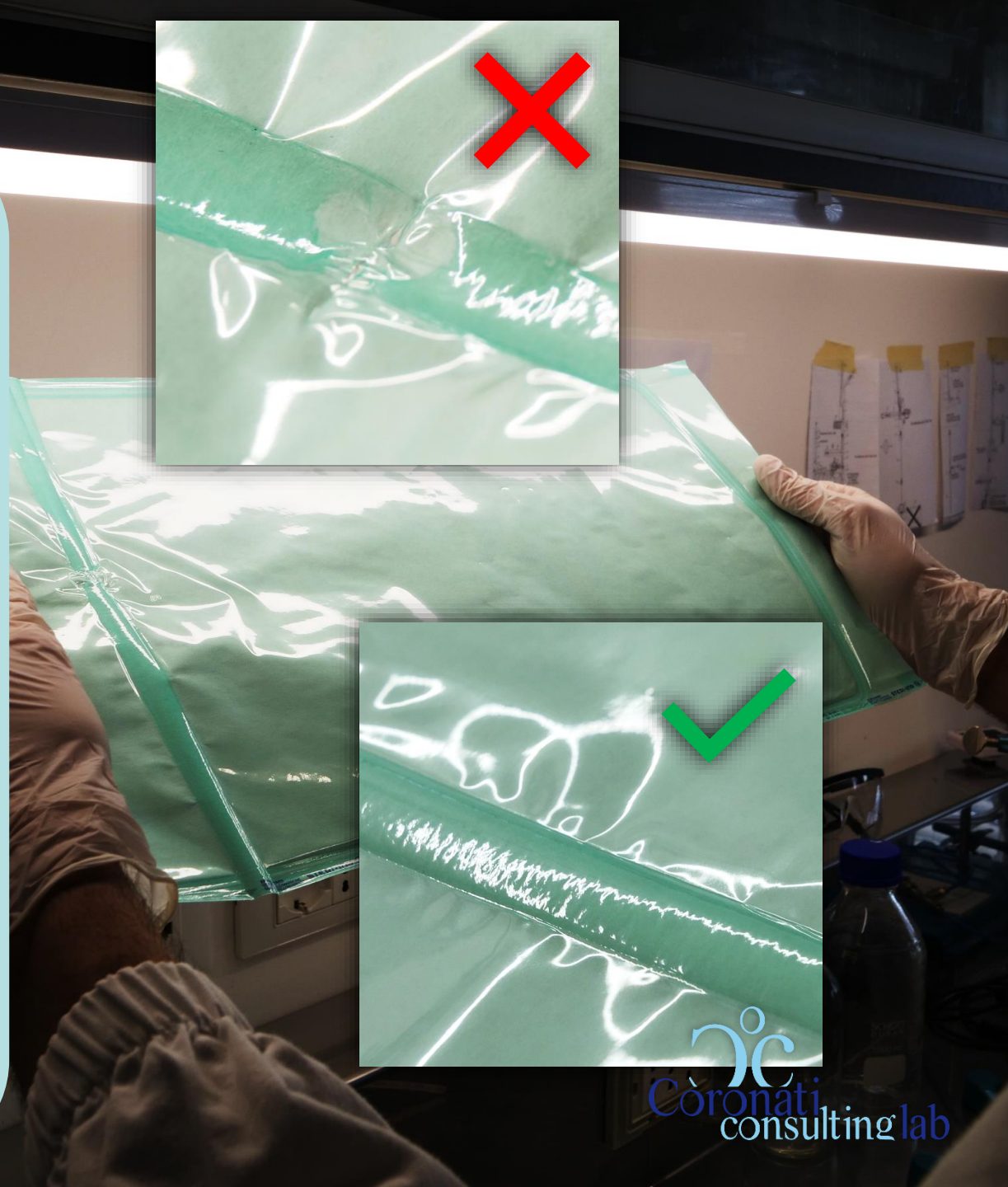
ISO 17025 ACCREDITED

Scope:

This test provides a qualitative visual inspection method to evaluate the characteristic appearance of intact welds to determine the presence of defects which may affect the integrity of the packaging.

Reference Standard:

ASTM F1886/F1886M – 16 (2024): Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection



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ACCELERATED AGING

ISO 17025 ACCREDITED

Scope:

Possible effects of the passage of time on the sterile barrier system shall be investigated. Accelerated aging protocols can be used until data from real time aging are available.

Reference Standard:

ASTM F 1980-21:

Standard guide for Accelerated Aging of Sterile Barrier System for Medical Devices

STERILITY TEST

ISO 17025 ACCREDITED

Scope:

Qualitative determination of the microbial load in medical devices subjected to the sterilization process or produced in aseptic conditions.

Reference Standard:

European Pharmacopoeia 2.6.1
USP <71>

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CONSULTANCY SERVICES

Coronati Consulting also provides the following services:

- Validation Plan
- Protocols (OQ/PQ)
- Sampling Plan
- Risk Analysis
- Gap Analysis
- Biocompatibility (ASTM F2475)

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