



ILAC MRA **2023** Annual Report



Introduction

The International Laboratory Accreditation Cooperation (ILAC) and its accreditation body members invest significant effort and resources to maintain the integrity and consistency of the ILAC Mutual Recognition Arrangement (MRA), also known as the ILAC Arrangement, through a peer evaluation process. The result of this process is an evaluation report that sets out the detailed activities carried out as part of the peer evaluation process, to ensure that regulators, specifiers, and businesses can have confidence in the Arrangement.

The focus of this document is to report on the activities undertaken by ILAC, in collaboration with IAF, and the evaluation activities undertaken by these organisations or the Regional Accreditation Groups (RAGs). This report also outlines the activities of the Arrangement Council and the Arrangement Management Committee (AMC) (in collaboration with IAF under the Joint Management Committee).



About ILAC

ILAC is the international authority on laboratory, inspection body, reference material producer, proficiency testing provider and biobank accreditation, with a membership consisting of accreditation bodies, regional cooperation bodies and stakeholder organisations throughout the world.

Note: Laboratories including medical laboratories, inspection bodies, reference materials producers, proficiency testing providers and biobanks are commonly referred to as conformity assessment bodies or CABs.

ILAC provides the infrastructure that supports the world-wide demonstration of competence and equivalence of accredited conformity assessments bodies (CABs).

The essential purpose of accreditation is to provide confidence in the competence of CABs which support activities within and between economies including trade, protection of health, safety and the environment, for the public benefit.

The ILAC Arrangement is an international, multilateral mutual recognition arrangement for accreditation bodies. Participating accreditation bodies agree to promote acceptance of the

equivalence of calibration, test and inspection reports, proficiency testing programs and reference materials, produced by accredited facilities (CABs). Each accreditation body undergoes peer evaluation according to international standards and ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

**Note: The ILAC Arrangement is currently in the process of being extended to include the accreditation of biobanks as detailed later in this report under: On-going development of the ILAC MRA.*

ILAC, the recognised regional cooperation bodies of ILAC and the accreditation body signatories all commit significant time and resources through the peer evaluation process to maintain and improve the integrity, consistency and recognition of the ILAC Arrangement. This annual report provides information on the activities carried out as part of the peer evaluation process to ensure that regulators, users and consumers of laboratory and inspection data, proficiency testing programs and reference materials are able to maintain confidence in the results produced under the ILAC MRA.



The ILAC MRA

The ILAC MRA is an agreement signed by the signatory accreditation bodies to recognise the equivalence of the accreditation schemes operated within the scope of their signatory status.

The aim of the ILAC MRA is to provide recipients of laboratory and inspection body reports and users of proficiency testing programs, and reference materials confidence that the results, programs and materials have been produced by a technically competent CAB that has been accredited by an accreditation body that is a signatory to the ILAC Arrangement.

The ILAC MRA provides assurance that CABs in different economies are operating to the same international standards. The accreditation schemes offered by the accreditation bodies that are signatories to the ILAC MRA are all evaluated on an on-going basis to confirm their currency and relevance.

The details of the ILAC MRA are included in ILAC P5 ILAC Mutual Recognition Arrangement: Scope and Obligations available from <https://ilac.org/publications-and-resources/ilac-policy-series/>

Scope of the ILAC MRA

The scope of the ILAC MRA currently covers the following accreditation schemes:

- Calibration laboratories using ISO/IEC 17025;
- Testing laboratories using ISO/IEC 17025;
- Medical testing laboratories using ISO 15189;
- Inspection bodies using ISO/IEC 17020;
- Proficiency testing providers using ISO/IEC 17043;
- Reference material producers using ISO 17034; and,
- Biobanks using ISO 20387 (on-going).

Signatories to the ILAC MRA

The ILAC MRA is based on the established and peer evaluated multi-lateral arrangements (MRA/MLAs) of the recognised regional cooperation bodies.

Accreditation bodies that are Associate members of ILAC and a signatory to a recognised regional MRA/MLA are accepted as signatories to the ILAC MRA.

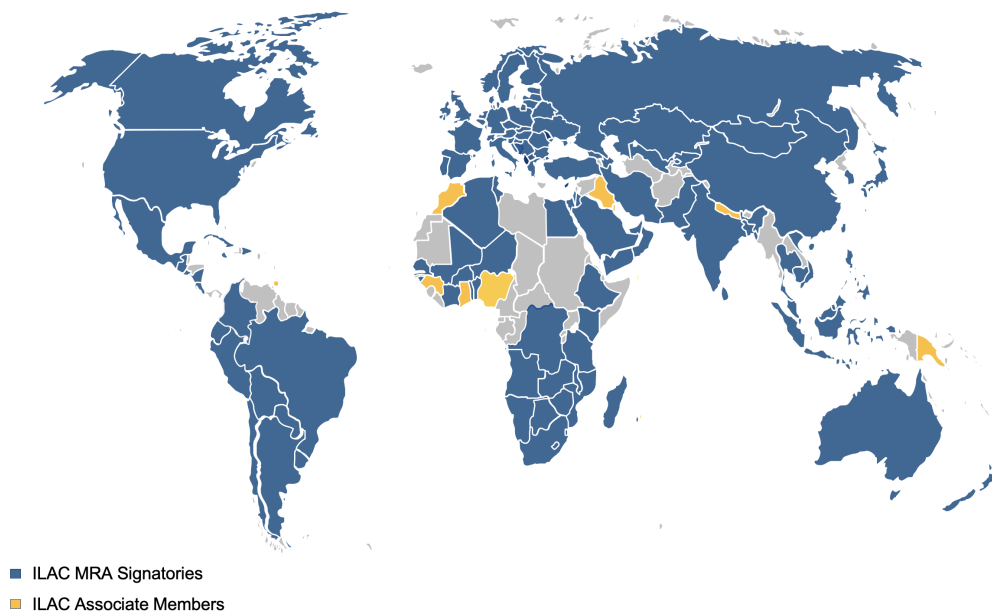
Where there is no recognised regional cooperation body available to which an accreditation body can be a member or where the scope of recognition of a recognised regional cooperation body does not include all the available schemes, ILAC provides the opportunity for these accreditation bodies to be peer evaluated as an unaffiliated accreditation body.

As of December 2023 there were:

- 6 regional cooperation bodies recognised under the ILAC MRA - African Accreditation Cooperation (AFRAC), Asia Pacific Accreditation Cooperation Incorporated (APAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA), Inter-American Accreditation Cooperation (IAAC) and Southern African Development Community Cooperation in Accreditation (SADCA);
- 114 accreditation body signatories to the ILAC MRA via the MRA/MLAs of these recognised regional cooperation bodies from 118 economies.



Coverage of the ILAC MRA (31 Dec 2023)



Significant changes were made to the list of signatories to the ILAC MRA in 2023, via the recognised regional processes, included the addition of the following new signatories for the accreditation scopes listed as:



- Vietnam Institute of Accreditation (VACI), Vietnam for calibration and testing (ISO/IEC 17025);
- National Bureau of Agricultural Commodity and Food Standards (ACFS), Thailand for inspection (ISO/IEC 17020);
- Iranian Association of Clinical Laboratory Doctors (IACLD), Iran for medical testing (ISO 15189);
- Federation for Development of Accreditation Services, (FDAS), India for testing (ISO/IEC 17025) and medical testing (ISO 15189);
- Cambodian Accreditation National Council - General Department of Accreditation of Cambodia (CANC-GDAC), Cambodia for testing (ISO/IEC 17025); and,
- Non-Profit Association Estonian Centre for Standardisation and Accreditation (EAK), Estonia for calibration and testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020).

In addition, the following signatories to the ILAC MRA extended their scope in 2023:

- Accreditation Body of Serbia (ATS), Serbia extension for PTP (ISO/IEC 17043);
- Georgian Accreditation Center - The Unified National Body of Accreditation (GAC) Georgia extension for PTP (ISO/IEC 17043);
- International Accreditation Service, Inc (IAS) extension for medical testing (ISO 15189);
- Korea Laboratory Accreditation Scheme (KOLAS), Korea extension for RMP (ISO 17034) and PTP (ISO/IEC 17043);
- Norsk akkreditering (NA), Norway extension for RMP (ISO 17034);
- Saudi Accreditation Center (SAAC), Saudi Arabia extension for medical testing (ISO 15189);
- Servicio de Acreditación Ecuatoriano (SAE), Ecuador extension for medical testing (ISO 15189);
- Standards Council of Canada (SCC) Canada extension for PTP (ISO/IEC 17043); and,
- Tunisian Accreditation Council (TUNAC), Tunisia extension for medical testing (ISO 15189).

The current version of the list of signatories is available from <https://ilac.org/ilac-mra-and-signatories/>

The ILAC website includes a dedicated signatory search function (<https://ilac.org/signatory-search/>). This directory of the signatories to the ILAC MRA is searchable by accreditation body name or acronym, economy and scope of signatory status to the ILAC MRA. In addition, this search facility can be hosted directly on your website (via the code provided at the above link) to ensure your customers and stakeholders have access to the latest information on the signatories to the ILAC MRA.

» ILAC MRA AND SIGNATORIES

SEARCH SIGNATORIES PASTE THIS CODE TO YOUR WEBSITE TO HOST THE ILAC MRA SEARCH FACILITY

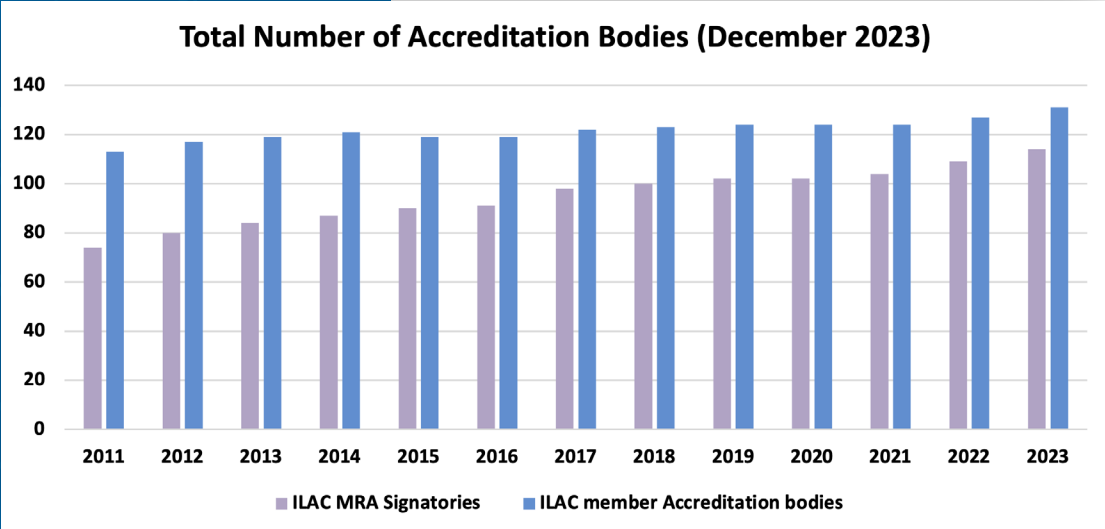
Accreditation Body: Acronym: Economy: Scope:

ACCREDITATION BODY:

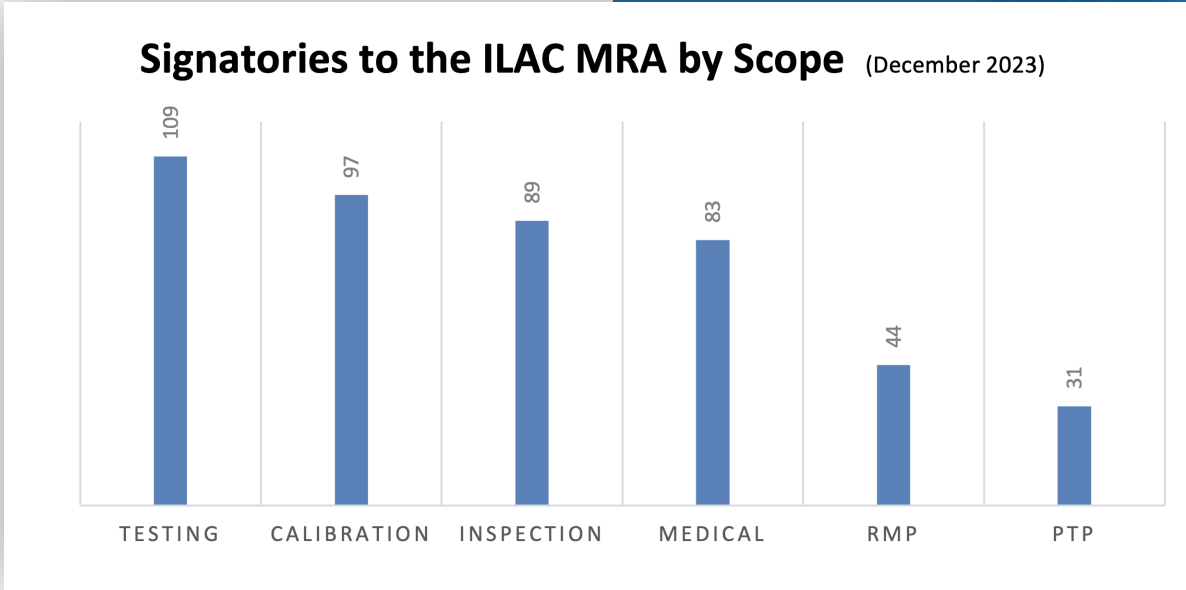
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Global Growth

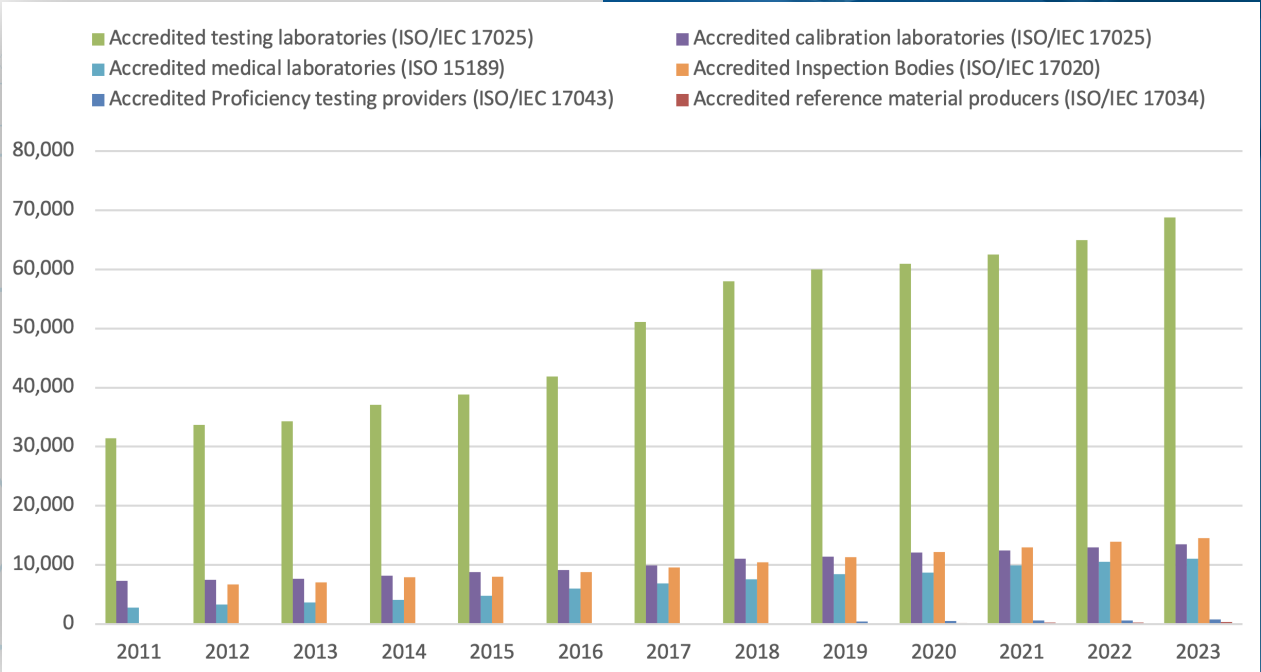
In recent years, there has been a steady geographic expansion of the membership of ILAC through the number of accreditation bodies that have become members of ILAC.



The number of signatories to the ILAC MRA by scope of signatory status is shown below.



Total Number of Accredited Conformity Assessment Bodies (CABs) 2011 - 2023



The ILAC MRA Mark

The signatories to the ILAC MRA and their accredited CABs are able to use the ILAC MRA Mark via licensing agreements and in accordance with ILAC R7 Rules for the Use of the ILAC MRA Mark.

When used by a CAB on reports or certificates in combination with the accreditation body's accreditation symbol, the Mark demonstrates that the calibration, testing, inspection, proficiency testing provision or reference material production activity has been carried out by an organisation that is accredited by an ILAC MRA signatory for that activity, providing assurance and confidence in the results, programs and materials.



Evaluations

Accreditation bodies are admitted to the ILAC MRA following a stringent evaluation of their operations by a peer evaluation team which is tasked with ensuring the accreditation body fully complies with both international standards and ILAC requirements.

ILAC, and its regional cooperation and accreditation body members, invest significant time and resources to operate a robust peer evaluation process. It is an on-going process, with full re-evaluations carried out every four years, covering all economies and all activities covered by the ILAC MRA.

During 2023, the following evaluation activities occurred:

- scheduled re-evaluation of APAC was completed in August 2023;
- scheduled re-evaluation of ARAC was completed in April 2023;
- scheduled re-evaluation of EA was completed in December 2023;
- scheduled re-evaluation of IAAC was completed in February 2023; and,
- initial evaluation of SADCA was completed in March 2023.

In addition to these evaluations carried out directly by ILAC, the recognised regional cooperation bodies carried out the following peer evaluation activities in 2023:

- AFRAC - 3
- APAC - 18
- ARAC - 2
- EA - 13
- IAAC - 12
- SADCA - 1

Evaluator Resources

Ten evaluators and eight report reviewers were involved in the evaluation activities directly carried out by ILAC in 2023.

Decisions by the ILAC Arrangement Council

The ILAC Arrangement Council consists of representatives from the accreditation bodies that are signatories to the ILAC MRA as well as Associate members of ILAC, the regional cooperation bodies and a stakeholder member. It is responsible for the decisions relating to the signatory status of both regional cooperation bodies and unaffiliated accreditation bodies to the ILAC Arrangement. On completion of a peer evaluation, the final report prepared by the evaluation team and including information on the close out of any findings is forwarded to the members of the ILAC Arrangement Management Committee (AMC). This committee is responsible for the day-to-day management of the ILAC MRA. The report is thoroughly reviewed by this committee including, where necessary, seeking additional information from the evaluation team to clarify any issues. On completion of the review process the AMC prepares a recommendation for consideration by the Arrangement Council.

The ILAC Arrangement Council considered five evaluation reports based on the recommendation of the ILAC AMC in 2023.

On-going development of the ILAC MRA

ILAC is committed to extending the ILAC MRA and improving the MRA in technical terms. A resolution was adopted at the ILAC General Assembly in October 2019 noting that the standard applicable to biobank facilities for the purpose of accreditation is ISO 20387 Biobanking - General requirements for biobanking as a standalone standard. A further resolution was adopted in November 2021 endorsing the recommendation to extend the ILAC MRA to include the accreditation of biobanking as a Level 2 activity, to the criteria specified in the Level 3 normative document, ISO 20387. The applicable ILAC MRA documents to support the implementation of this resolution were revised and subsequently published in June 2022. The ILAC AMC accepted an application from APAC in December 2022 for an extension of the APAC recognition to the ILAC MRA to include the accreditation of biobanks. The evaluation activities for this extension will be carried out in 2025. On the successful completion of an evaluation of a region for this developing field the ILAC MRA will be able to be extended to include the accreditation of biobanks using ISO 20387.

Collaboration with IAF

• In 2023, ILAC continued to improve its collaboration with IAF. There are no longer separate meetings of ILAC AMC and IAF MLA MC. These have been completely replaced by the Joint Management Committee (JMC) meetings.



This provides for a better understanding of the few different requirements and the many commonalities in the MLA/MRA area between the two organisations. The JMC manages all the peer evaluations activities and will contribute to the establishment of a single Arrangement for Global Accreditation Cooperation (GLOBAC), the new single International Organisation for Accreditation.

In addition, the JMC initiated a revision of:

- IAF/ILAC A1 – IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Regional Group, with the intention to improve the evaluation methodology for RAGs.
- IAF/ILAC A2 – IAF/ILAC Multi-lateral mutual recognition arrangements (Arrangements): Requirements and procedures for evaluation of a single accreditation body, a workshop was held in May 2023 to consider changes and explore a risk-based approach to evaluation. The outcome from the discussion on the introduction of the risk-based approach, will be taken into account in the revision of IAF/ILAC A2.
- The JMC also accepted a proposal for a training package to be developed to support those evaluators asked to undertake evaluations of Regional Accreditation Groups. This training package will be developed and delivered in 2024.

International standards

There were no transition periods in place for the international standards included in Level 1 or 3 of the ILAC MRA in 2023.



New and revised publications

ILAC regularly publishes requirements and information to support accreditation and conformity assessment processes. During 2023, ILAC issued the following publications:

- *ILAC-P5:11/2023 ILAC Mutual Recognition Arrangement: Scope and Obligations.*
- *ILAC P8:11/2023 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies.*
- *ILAC-R6:11/2023 Structure of the ILAC Mutual Recognition Agreement and Procedure for Expansion of the Scope of the ILAC Arrangement.*

On-going promotion of the ILAC MRA

Case studies from economies all around the world continue to be added to the publicsectorassurance.org website to illustrate the value of accreditation in key policy areas and as a tool in supporting government officials and regulators deliver results. The site also links the case studies to the United Nations Sustainable Development Goals (SDGs).

The site also contains links to independent research and information to provide additional supporting evidence.

By showcasing the policy areas where accreditation of conformity assessment is, and can be used, such as economic development, healthcare, environmental protection, energy, food safety, construction, crime and security, the site continues to provide inspiration for central government, local government and regulators to deliver positive benefit by the use of more conformity assessment tools.

Supporting the needs of government, regulators and the public sector remains a core objective of the conformity assessment community.



In addition, the number of case studies, research papers and supporting materials demonstrating the monetary value of standards, conformity assessment and accreditation for businesses continues to grow on the business benefits website.



World Accreditation Day 2023

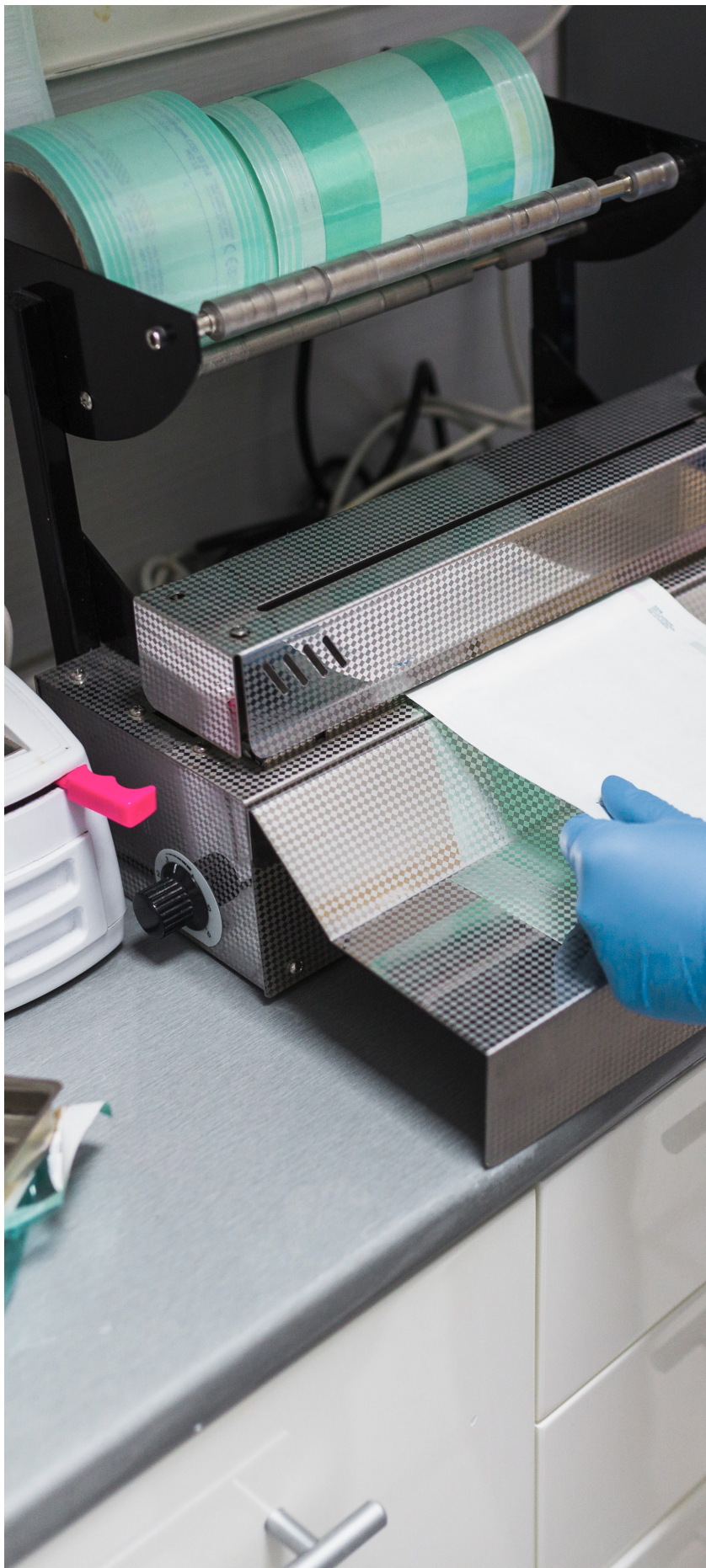
The global accreditation community celebrates each year with the World Accreditation Day on 9 June to raise awareness of the value that accreditation plays in facilitating global trade, in checking that products and services are fit and safe for use against a standard, a code or practice or regulatory requirements.

World Accreditation Day was celebrated on 9 June 2023 with the theme:

Accreditation: Supporting the future of Global Trade.

This theme focused on how accreditation supports the United Nations Sustainable Development Goals (SDGs) 1, 2, 3, 5, 8, 9, 10, 14, and 17.

It provided the opportunity for ILAC and IAF members to share examples with stakeholders, regulators and consumers of how accreditation and conformity assessment are adapting to advances in technology, changes in consumer behaviours and regulatory environment, new trust mechanisms, and changing business models.



ADDITIONAL INFORMATION

The ILAC website provides information on the ILAC MRA and also includes brochures and information on World Accreditation Day celebrated on 9 June each year.

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