

IAF's Global Certificate Database

Supporting – "ISO 13485 Certified Supply Chains" GHWP 2023

IAF CertSearch the global certificate database.

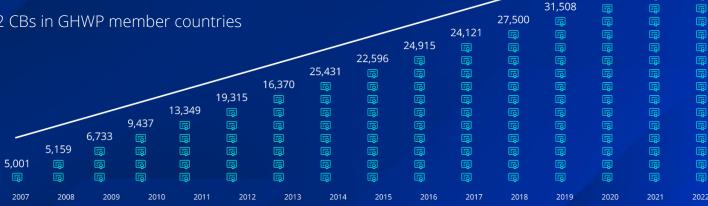
"Our mission is to ensure all valid accredited certifications can be efficiently verified by businesses and regulators around the world to support quality, safe and sustainable global trade"



The demand for Medical Device compliance, governance and transparency is growing significantly.

- > 40,000 ISO 13485 certified sites globally
- 82 Accreditation Bodies & 240 Certification Bodies who accredit / issue ISO 13485 certification
- Countries with largest number of certified sites : USA, China, Germany, Italy, France, UK, Japan, Chinese Taipei, India, Switzerland, Korea (Republic of)
- Fastest growing countries for ISO 13485 China (27% pa) and India (29% pa)
- GHWP 27 ABs and 92 CBs in GHWP member countries





ISO 13485 Certified Sites Globally ISO survey & IAF CertSearch data – 2022 estimate

42,353

38.503

34.954

Whilst accredited certifications are at an all time high, so are **counterfeit &** fraudulent certifications and a lack of digital solutions to verify certifications creating risk for corporates, regulators and financial institution & eroding value for those who have valid certifications.







Withdrawn Certificates



Valid Certificates

IAF members voted to ensure all MS certificates globally are uploaded to the database.

- July 4th August 4th 2022 IAF members conclusively voted to mandate the uploading of all valid accredited MS certificates to the database.
- IAF has established a TC committee to draft the mandatory document to enforce compliance by ABs & CBs.
- The mandatory document will be completed circa August 2023 and transition will commence thereafter.



Benefits for GHWP members and regulators

IAF members voted for the following benefits for regulators

- Free to use for approved regulators
- Regulators will receive unlimited certificate verifications
- Real time API integration
 - this means that regulators can connect their internal systems and certificate verification of all suppliers can happen in bulk, automatically in real time.
- Watchlist benefits
 - Receive real time alerts / notifications on suppliers certificates of interest i.e. importers
- Access to a support team to help regulators identify and deal with counterfeit certifications



Regulators can take action in real time.

Via a "watchlist" IAF CertSearch automatically informs organizations when a certification status changes i.e. suspended, withdrawn, expired.

This enables regulators be proactive and mitigate risk.

Watchlist

ABC Health and Logistics, Site 12 has been withdrawn
Healthway, Site 1 has been suspended

Realth Matters, Site 12 has been withdrawn

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Aggregating the worlds ISO 13485 certification information, helps regulators and businesses gain full visibility of their supply chains via the certification platform, enabling real time verification and monitoring of each and every certified site.



How GHWP Members can support the IAF

Over 10,000 business and regulators from 66 countries expressed support for the global databases to include all certificates so it is truly reliable.

Regulators such as ANAC, the Italian regulator for public procurement and corruption has since mandated that any supplier participating in public procurement in Italy must have their certificate include in the IAF global database.

We are seeking support from other GHWP members to also require any company who shares an ISO 13485 certificate to them, they will require the ISO 13485 certificate to be included in IAF CertSearch so the regulator can verify it is 100% legitimate and valid.

Certifications and conformity assessment records hold their value when they can be verified to be legitimate and accurate.



Il Presidente

international Accreditation Forum (IAF Box 1811, Cheltes Quebec 198 141 Emanuele Filva (IAF Chair) <u>exista@accredia.ib</u> secretary@at.In

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Object

Indications regarding the verification, for the purposes of obtaining the qualification certificate, of quality certifications issued by Certification Bodies accredited by Accreditation Bodies adhering to the international IAF MLA agreements.

Obligation for certification bodies accredited ISO/IEC 12021-1 by Accreditation Bodies IAF MLA signatories to provide certification data to the IAF database (IafCertsearch) in order to allow verification by ANAC

Dear Sirs,

States.

following the Statement of the ANAC PRESIDENT of 9 June 2021', we inform you that the Authority has adopted the Statement of 21 december 2022 (enclosed). The new Statement provides clarifications regarding the verification of the quality certification issued by Boldes accorded by Entities adhering to the international IAF MLR agreements, for obtaining the certification of qualification and participation in the assignment provide as

Ardici Ba, paragraph 4, of the ligibilities derive of 18 dpri 2016, n. 597, Phenichter the public contract codel provides that the Attestation Bodies (SDA) for the qualification of economic operators should certify the possession of quality spatter certifications, compliant with the European standards of the URI EI SO 3000 series and with current bigibilition national, issued by accordited entities in accordance with the European standards of the URI EI SO 3000 standards of the URI EI SO 4000 series and the URI EI BI 5000 contract and the URI EI BI 5000 series and the URI EI BI 5000 contract and the URI EI BI 5000 series and the URI EI BI 5000 contract and the URI EI BI 5000 series and the URI EI BI 5000 contract and the URI EI BI 5000 series and the URI EI BI 5000 contract and the URI EI BI 5000 series and the URI EI BI 5000 contract and the URI EI BI 5000 series and the URI EI BI

Article 63 of the decree of the President of the Republic n. 207/2010⁶, in force on a transitional basis by virtue of article 216, paragraph 14, of the public procorrented code, establishes that, for the purpoise of qualification in classifications higher than II, companies must have the company quality system compliant with European standards of the UNI ENI 50 9000 series, issued by accented extilication bodies (in accordance with the

¹ https://www.anticorruzione.it/-/comunicato-del-presidente-del-9-giugno-2021

² https://www.anticorruzione.it/-/comunicato-del-presidente-del-9-giugno-2021

¹ https://www.anticorruzione.it/-/comunicato-del-presidente-del-9-giugno-202

Thank you

Appendix

What is an accredited certification

International Accreditation Forum (IAF)

Provides oversight & governance of Multilateral Recognition Agreement (MLA)

Accreditation Body (AB) _____

 Recognized by IAF as signatory of MLA

• Accredits CBs

Certification Body (CB)

Accredited by AB to certify organizations

Organization

Achieves accredited certification to Management System Standard(s)



Users

Business, Regulator, Asset owner, Government

Formal Letters of Support



Thomas Kaiser, AIRBUS

Ranjit Thakur, 3M



Crystal Sharp, DuPont



Kevin Bourne, S&P Global



Murray Clair, Nupress Pty Ltd.



Maria Silber, Satair



Ali Al dalaan, Saudi FDA



Beth Ford , AT&T Services, Inc.



Paul Scheihing, United States Department of Energy



Bob Fraser, Natural Resources Canada



Rana Ghoneim, United Nations Industrial Development Organization (UNIDO)



Brad Hunt, Rimes **Chief Executive Officer**



Brian Motherway, International Energy Agency

ISO Edwin Fletcher, ISO/TC 67/WG 2





Alan Daniels

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🕝 GATAN

Charles A Nigro , Gatan, Inc.

Global Harmonization Working Par Mr Ali M. AL-DALAAN



Ms. Graziella F. Siciliano, Clean Energy Ministerial



Archt. Marci Gasparri, CONSIP



Fred Freedman, DTA



Brian Geer

Material Exchange

Kelly Burton, Material Exchange



Ken Koffman, QuEST Forum



Jeffrey Hunt, ISO/TC 176

EFAC

Ivan Savov, EFAC

Marsh

Wayne Terry, Association of British Certification Bodies (ABCB)

ecovadis

Pierre-Francois Thaler, Ecovadis

Paul Johnson, Marsh

(**gìvv**able Frances Atkins, givvable Pty Ltd

Your Supplier rırocapıtal

Gary Storr, Trust Your Supplier

Wayne Morris, FIFO Capital Group of Companies



Marco Preti



Dr. John Gattorna, Gattorna Alignment



Sreedhara HN, Triton



Miriam Wilson, Shell