



IAF's Global Certificate Database

Supporting – “ISO 13485 Certified Supply Chains”
GHWP 2023

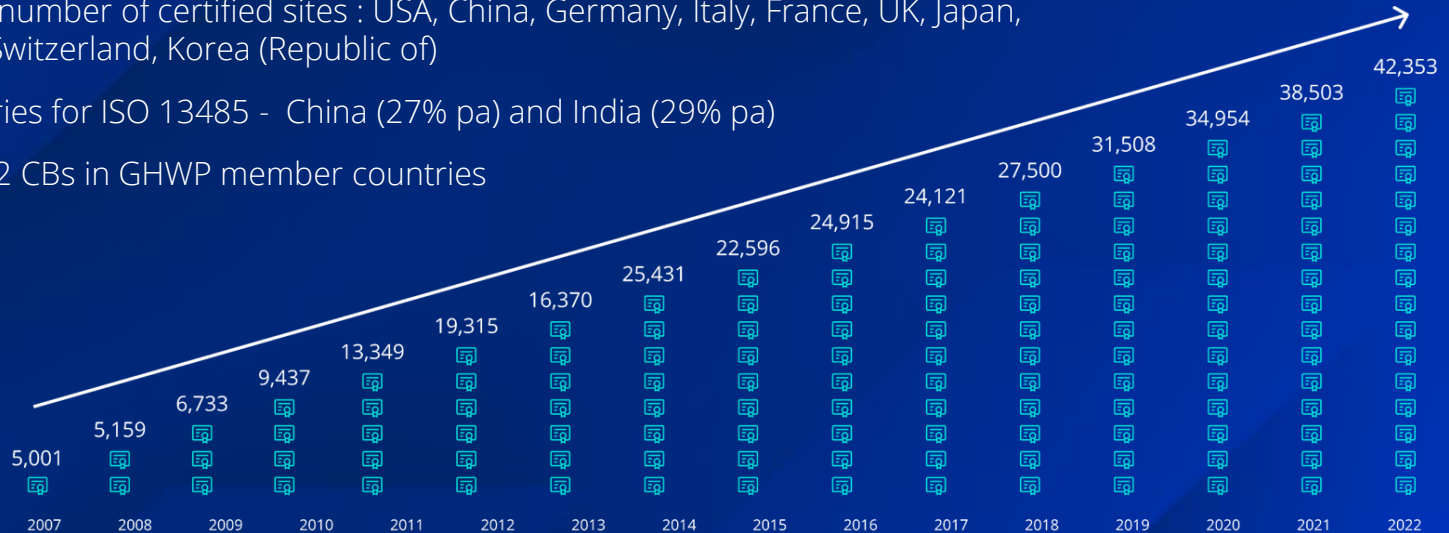
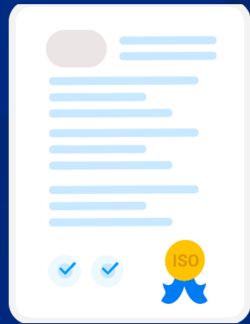
IAF CertSearch the global certificate database.

“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.

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.



> 20,000 counterfeit & fraudulent certifications have been identified by IAF CertSearch this year.



Counterfeit Certificates



Withdrawn Certificates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.

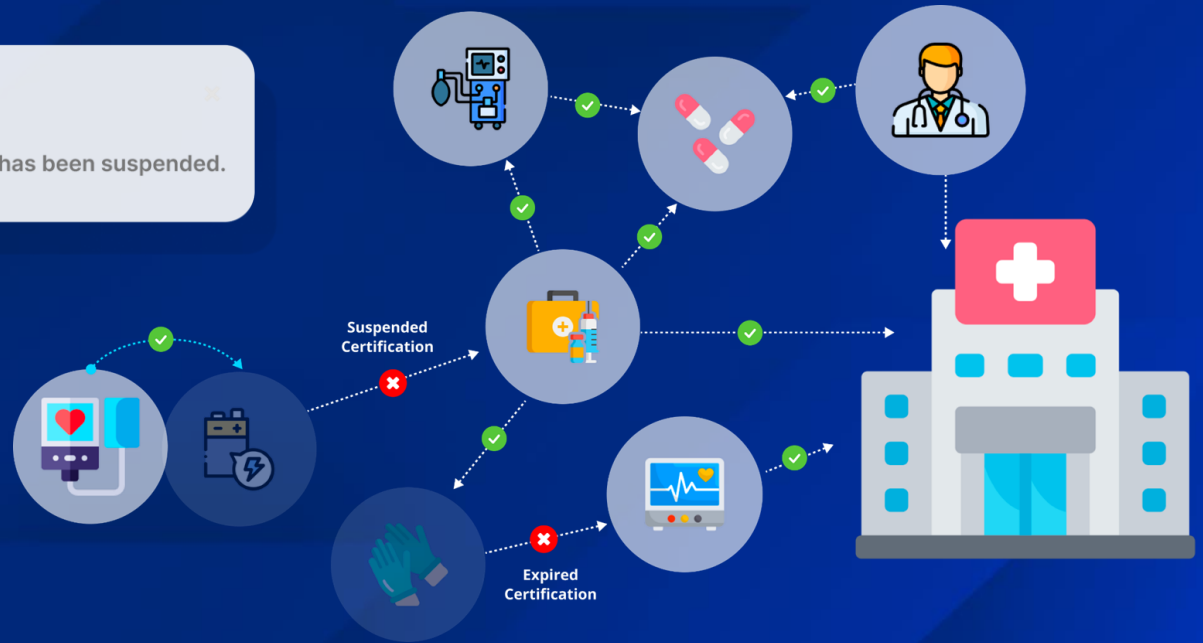


Aggregating the worlds ISO 13485 certification information, helps regulators and businesses gain full visibility of their supply chains via the certification platform, enabling real time verification and monitoring of each and every certified site.



Notifications

❌ Health Matters, located in India has been suspended.



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.



Thank you

Appendix

What is an accredited certification

International Accreditation Forum (IAF)

Provides oversight & governance of Multilateral Recognition Agreement (MLA)

Accreditation Body (AB)

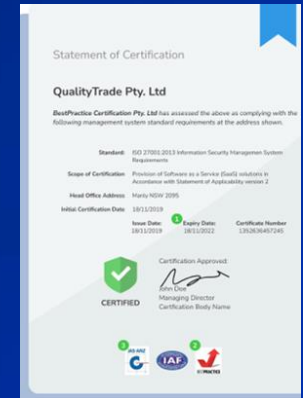
- Recognized by IAF as signatory of MLA
- Accredits CBs

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



Ranjit Thakur, 3M



Thomas Kaiser, AIRBUS



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



Edwin Fletcher, ISO/TC 67/WG 2



James Bruin



Alan Daniels



Charles A Nigro , Gatan, Inc.



Mr Ali M. AL-DALAAAN



Ms. Graziella F. Siciliano, Clean Energy Ministerial



Arch. Marci Gasparri, CONSIP



Fred Freedman, DTA



Brian Geer



Kelly Burton, Material Exchange



Ken Koffman, QuEST Forum



Jeffrey Hunt, ISO/TC 176



Ivan Savov, EFAC



Paul Johnson, Marsh



Wayne Terry, Association of British Certification Bodies (ABCB)



Pierre-François Thaler, Ecovadis



Frances Atkins, givvable Pty Ltd



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