

English translation for information purpose only

EQWAL GROUP POLICY

ECONOMIC SANCTIONS AND EXPORT CONTROL

Reference	Version	Effective date	Classification
GRP-POL-SANC-001	1.0		Confidential
Group Legal & Compliance Department	1.0		Group

Eqwal Group commitment

The Eqwal Group (The “**Group**”) is committed to operating in strict compliance with applicable laws and regulations on international economic sanctions and export control laws, in line with its mission to provide patients around the world with high-quality orthopaedic medical device products and components, as well as innovative digital solutions.

Failure to comply with this policy exposes the Group and its employees to sanctions criminal, administrative and civil consequences, as well as major reputational risks.

1. Purpose and scope:

This Economic Sanctions and Export Control Policy (hereinafter "**the Policy**") defines the minimum requirements that all entities, employees (and third parties acting on our behalf) of the Eqwal Group must adhere to ensure compliance with the economic sanctions regimes applicable worldwide.

Economic sanctions are financial, trade, and travel-related restrictions targeting individuals, entities, or countries ("**Sanctioned Parties**"). Countries may be subject to comprehensive sanctions (each, an "**Embargoed Country**") or non-comprehensive sanctions (each, a "**Restricted Country**").

1.1 Objectives:

- Prevent any transactions with individuals, entities or countries subject to economic sanctions.
- Ensure compliance with export control laws applicable to orthopaedic medical products and devices (orthotics and prosthetics).
- Protect the Group, its employees and its partners against the legal, financial and reputational risks associated with economic sanctions.
- Ensure the continuity of humanitarian and medical activities in sensitive areas, in line with exemptions under sanctions regimes.

1.2 Scope of application:

This Policy applies, without exception, to:

- All the Group's subsidiaries and branches worldwide.
- All of the Group's employees, including managers, officers and directors.
- Third parties acting in the name or on behalf of the Group (distributors, agents, subcontractors, service providers).
- All the commercial, financial and operational activities of the Group, including research and development, manufacturing, distribution and after-sales service of orthopaedic medical products and devices.

Sectoral particularity — Orthopaedic medical devices

Orthoses and prostheses are **medical devices** within the meaning of Regulation (EU) 2017/745. Under sanctions regimes (EU, UN, US), orthoses and prostheses may benefit, under certain conditions, from **humanitarian exemptions**. Particularly, the UN Security Council Resolution 2664 (2022) established a permanent humanitarian exemption to asset freeze measures across United Nations sanctions regimes, as well as applicable licensing regimes. established a permanent humanitarian exemption.

However, these derogations are neither **general nor automatic** and may require specific authorisations to be obtained in advance. As a result, the **Group's Legal/Compliance Department must be systematically consulted** before any operation involving a country under sanctions.

2. Regulatory framework:

2.1 Applicable Penalty Regimes:

The Group is subject to sanctions regimes issued in particular by the following authorities:

Authority	Organization	Main applicable texts
United States	The Office of Foreign Assets Control ("OFAC») (Treasury)	IEEPA, TWEA, Lists SDN, OFAC Country Programs
European Union	Council of the EU / Directorate-General for Financial Stability, Financial Services, and Capital Markets Union (DG FISMA)	EC Sanctions Regulations, Dual-Use Regulation
United Kingdom	Office of Financial Sanctions implantation OFSI (HM Treasury)	Sanctions and Anti-Money Laundering Act 2018
United Nations	UN Sanctions Committee	Security Council Resolutions
France	General Directorate for Internal Security (DGSI / Treasury)	Monetary and Financial Code, Asset Freezing Decrees
Other States	National authorities	Local laws applicable by jurisdiction

2.2 Specific regime (Dual-use items):

2.2.1. General Export Control Regime:

A dual-use item is any good, technology or software that can have both civilian and military purposes. Dual-use items are an important piece to import and export control laws, as they serve as a mechanism to comply with international treaties obligations to not transfer items or materials that could contribute to the proliferation of mass weapons.

Each country will provide in its import and export control laws and policies which items will to be deemed "dual use" items. This prevents the transfer of these "dual use" items from one country to another and restricts "dual use" items from entering the country. The export and trade of "dual use" items may also be restricted through sanctions imposed by an individual country, regional authority, or the United Nations Security Council. Orthopaedic medical products and devices marketed by the Group may be subject to export control regulations and applicable economic sanctions regimes.

The classification of products depends on their nature and technical characteristics. Orthoses, prostheses and components of medical devices are generally classified under the customs headings applicable to medical devices and are usually neither considered dual-use items nor subject to specific export licensing. However, their export remains subject to compliance with economic sanctions, embargoes, geographical restrictions and asset freezes applicable to sanctioned countries, entities or individuals.

On the other hand, certain accessories, manufacturing equipment, computer-aided design software (CAD/CAM), related technologies, or specific electronic components may be subject to additional regulatory requirements, such as when exported to sanctioned jurisdictions or when they fall under specific export control regulations. Items that can be used for both civilian and military purposes ("**dual-use items**"), as

well as items identified as sensitive under sanctions regulations, are subject to export controls when exported to destinations outside the European Union, with stricter controls applied to countries subject to sanctions.

2.2.2. United Kingdom Export Control Regime:

In the United Kingdom, medical devices and components of medical devices exported under HS code 9021 39 90 are generally not classified as dual-use or sensitive goods and are therefore, in principle, not subject to specific export controls. However, medical device accessories exported under HS code 9033 00 90 00 may be subject to certain control restrictions and therefore pose a higher risk under economic sanctions regulations.

The distinction between an integrated component of a medical device and a simple accessory is not always obvious. For example, a battery specifically designed for a medical device, which cannot be used with any other device without specific technical expertise and the absence of which would render the medical device unusable, could nevertheless be considered an accessory by the competent authority if it is easily removable, packaged separately and marketed as a stand-alone product.

The following operations have been identified in the UK as posing a potential risk to sanctions compliance:

Product Type	Description	Level of risk sanctions	Comments
Limb prostheses and related components	Upper and lower limb prostheses	Low	Exported under HS code 9021 39 90. These products are generally not considered dual-use items or subject to specific export controls.
Orthotic devices	Orthopedic insoles, custom shoes, orthotics, limb supports	Low	Exported under HS code 9021 39 90. Limited risk under sanctions regulations, subject to compliance with restrictions applicable to sanctioned countries or individuals.
Prosthetic Accessories	Batteries, electrodes, aesthetic coatings (gloves or cosmetic envelopes)	Medium	Although designed specifically for prosthetics, batteries and electrodes can be considered removable accessories and, in some cases, fall under more sensitive classifications under sanctions and export control regulations.

2.2.3 United States of America Regulations :

In the United States, the Export Administration Regulations (EAR) (15 CFR Parts 730–774), administered by the Department of Commerce’s Bureau of Industry and Security (BIS) are the country’s government rules that control the export, re-export, and transfer of commercial and dual-use items.

In the United States, dual-use items sit under the **Export Administration Regulations (EAR)** (15 CFR Parts 730–774), administered by the Department of Commerce’s Bureau of Industry and Security (BIS) — deliberately separate from the **International Traffic in Arms Regulations (ITAR)** (22 CFR Parts 120–130), which cover items designed or adapted specifically for military use and are administered by the State Department’s Directorate of Defense Trade Controls (DDTC). The dividing line matters operationally: an item that is inherently military-specific belongs on the ITAR US Munitions List, not the EAR’s dual-use list, and the two regimes have different licensing authorities, different exceptions, and different research carve-outs.

Within the EAR, dual-use items are organised on the **Commerce Control List (CCL)**, and each controlled item is assigned an **Export Control Classification Number (ECCN)** — a five-character code:

- the first digit (0–9) identifies the product category (e.g. 3 = electronics, 5 = telecommunications and information security, 9 = aerospace and propulsion);
- the following letter (A–E) identifies the product group (A = equipment/assemblies/components, B = test/inspection/production equipment, C = materials, D = software, E = technology);
- the final three digits point to the specific CCL entry and reason for control.

An item subject to the EAR that does not match any CCL entry is classified **EAR99** — a residual catch-all that is generally license-free to most destinations and end-users, though restricted parties, prohibited end-uses, and embargoed destinations can still require a license even for an EAR99 item. A researcher or export-control office determines an item’s classification either by self-classifying against the CCL’s Order of Review (15 CFR Part 774, Supplement No. 4), or by filing a formal Commodity Classification request with BIS, which returns a CCATS determination. See CASRAI’s dictionary entry on the [ECCN determination process](#) for the full mechanics of both paths.

3. Definitions

Term	Definition
Economic sanctions	Coercive measures decided by states or international organizations aimed at restricting trade, financial or diplomatic relations with specific countries, entities or individuals.
Designated Person	Any natural or legal person, group or entity listed at official sanctions list (e.g. OFAC SDN list, EU asset freezing list).
SDN List	The Specially Designated Nationals and Blocked Persons List identifies individuals, entities, and vessels targeted by U.S economic sanctions. The SDN List is created and updated by the U.S Treasury’s Office of Foreign Assets Control (l’OFAC). Reference : <u>OFAC Specially Designated Nationals List - Sanctions List Service</u>
Embargoed or Restricted Country	States subject to global or sectoral sanctions issued by the competent authorities (e.g., Iran, North Korea, Russia, Cuba, Syria, depending on the applicable regimes). Reference: <u>https://www.fatf-gafi.org/fr/countries/liste-noire-et-liste-gris.html</u>
Asset freeze	The extent to which a designated person’s assets and economic resources are tied up and cannot be made available.

Export Control	Regulations governing the international transfer of goods, services, software and technology, including dual-use items.
Export License	Administrative authorization required to export certain goods or technology to specific destinations or users.
Humanitarian Exemption	Exemption from sanctions regimes allowing the supply of medical, food and humanitarian goods to civilian populations in countries under sanctions.
Due Diligence	A set of checks and controls carried out before entering into a relationship or carrying out a transaction, aimed at identifying and reducing the risks of non-compliance.
Third parties	Any person or entity external to the Group with whom the Group has a commercial or contractual relationship (customers, distributors, agents, suppliers).
Beneficial owner	An individual who ultimately owns or controls a client entity or counterparty.
Risk of Circumvention	The risk that an apparently lawful transaction may be used to indirectly circumvent applicable sanctions through intermediaries or complex arrangements.

4. Responsibilities

Actor	Key Responsibilities
President	Approval of the Policy, supervision of the effectiveness of the sanctions compliance program, annual compliance report.
Finance Department	Approval of resources allocated to the compliance program, strategic decisions on sensitive markets.
	Control of financial flows, verification of financial compensation, application of payment restrictions.
Group Legal & Compliance Department	Operational oversight, complex case decisions, compliance reporting, policy updates.
	Regulatory monitoring, legal advice, management of license applications, internal investigations.
	Animation of the compliance program, training, monitoring and control, management of the alert system.
Marketing Department	Verification of business partners, reporting of risk situations, application of due diligence procedures.
Operations / Supply Chain Management / Procurement	Control of consignees of shipments, management of export licences for orthopaedic products.
Regional Managers / Subsidiaries	Local application of the Policy, reporting of risk situations, training of local teams.
All employees	Compliance with the Policy, reporting of any suspicious situations, participation in mandatory training.

5. Basic Obligations and Prohibitions:

5.1 Absolute prohibitions:

It is strictly forbidden for any entity or employee of the Group to:

- Entering into a transaction (sale, purchase, provision of services, transfer of funds) with a Designated Person on an applicable sanctions list.
- Carry out directly or indirectly commercial or financial operations with countries subject to global sanctions, **without specific prior authorization from the Management.**
- Export, transfer or retransfer Group products, services or technology to restricted destinations, end-users or end-uses, without a valid export license.
- Facilitate, participate in, or contribute to any operation intended to circumvent applicable sanctions, including through third parties.
- Providing financial, insurance, transportation or other related services to a Designated Person or in connection with a prohibited transaction.
- Deliberately delete, falsify or omit information in connection with any reporting to the relevant sanctions authorities.

5.2 Due Diligence Obligations:

5.2.1 Third-Party Verification:

Before entering into a commercial or financial relationship, the entities of the Eqwal Group must carry out a third-party verification according to the following procedures:

- Systematic verification of the names of all counterparties (customers, distributors, agents, suppliers) in the databases of updated official sanctions lists.
- Identification of the beneficial owner of the legal entities with which the Group enters into a relationship.
- Verification of the consistency between the declared activity of the third party and the nature of the products and services ordered (orthotics, prostheses, components).
- Documentation of all checks carried out in the Group's compliance management system.

5.2.2 Level of Due Diligence by Risk:

Risk Level	Criteria	Due diligence measures required
 Low	Non-sanctioned country, known third party, ordinary transaction	Verification of sanction lists, standard documentation, annual update of the profile.
 Moderate	Newly identified third party, moderate risk country, atypical transaction	Enhanced due diligence, beneficial ownership verification, compliance questionnaire, Compliance Manager validation.
 High	Countries under partial sanctions, third party not clearly identified, humanitarian exemption requested	Thorough due diligence, legal department validation, possible external opinion, licensing procedure, complete documentation.
 Prohibited	Countries under Global Sanctions, Identified Designated Person	Immediate blocking of the transaction, freezing of relations, notification of the Legal Department, report to the authorities if required.

6. Humanitarian and Medical Exceptions – Medical Devices

As Eqwal operates in the orthotic and prosthetic medical-device sector, certain products may qualify as medical devices under Article 2(1) of Regulation (EU) 2017/745.

However, the medical nature of an orthosis or prosthesis does not automatically exempt a transaction from applicable sanctions or export-control requirements. Any humanitarian or medical derogation, exemption or licence must be assessed on a case-by-case basis, taking into account the applicable sanctions regime, destination country, product classification, customer, end-user and end-use.

Before proceeding with any transaction involving a sanctioned or high-risk jurisdiction, Eqwal shall verify whether the transaction is :

- authorised without prior approval;
- covered by an applicable humanitarian or medical derogation or General Licence;
- subject to a specific authorisation or licence; or
- prohibited.

Particular attention shall also be given to applicable export-control and dual-use requirements, including **Regulation (EU) 2021/821**.

For certain jurisdictions, specific medical authorisations may be available under applicable sanctions regimes. For example, under U.S. sanctions regulations, certain medical devices may be authorised for export or reexport to Iran under **31 C.F.R. § 560.530** and to North Korea under **31 C.F.R. § 510.521**, subject to applicable conditions and exclusions.

Any uncertainty regarding the applicability or scope of a humanitarian or medical exception must be referred to the Legal & Compliance Department before the transaction is undertaken.

References: *see the Annex – References at the end of this document.*

7. Compliance procedures

The following screening and screening activities are in place:

- Regular monitoring by Eqwal Group's Legal & Compliance Department of developments in international sanctions and export controls, identified in particular through alerts and updates issued by the competent authorities, the Group's freight forwarders and the Chamber of Commerce.
- Annual assessment by Eqwal Group's Legal & Compliance Department of the risks related to sanctions and export controls to which the Eqwal Group is exposed, taking into account geopolitical and economic factors as well as changes in the Group's activities, customers, suppliers and product ranges.
- Solicitation on a sensitive project (a kind of review within the framework of a project).
- Training in export controls/economic sanctions for the employees concerned.
- The model distribution agreements require that the territories in which customers are authorized to distribute the products of the subsidiaries be clearly defined. Any customer distributing to end users outside of its authorized territory would be in breach of its contractual obligations, resulting in appropriate action being taken.

- Customer contracts include clauses requiring compliance with applicable regulations, including after validation by the Chief Financial Officer and the Group.
- Accounts receivable requiring a license are placed on hold, and shipments are only authorized after validation by the CFO and the Group.

The following measures must be taken when a risk of sanctions is identified:

- Carrying out due *diligence* on customers/suppliers, including a check against economic sanctions lists and asset freezing measures, in order to ensure the reputation of third parties.
- Verification of product classification, including HS Code, as well as the associated risk of penalties.
- License application (if applicable) for products that may be considered medical device accessories.
- Obtaining a statement from the customer confirming the location and civil status of the end customer, and, for customers operating in high-risk areas, a statement that the goods will not be re-exported to countries under economic sanctions after the sale.

8. Reporting, Alert Management and Incidents

8.1 Duty to Report:

Any employee, officer or representative of the Group who observes, suspects or identifies a violation of this Policy, or who becomes aware of an operation that may involve a Designated Person or an [Embargoed or Restricted Country](#), must promptly report to the competent persons, in accordance with the reporting channels defined below and the alert procedure in force within the Group.

8.2 Reporting Channels:

- Direct contact with the Compliance Officer of the entity or region concerned.
- Report to the Group's Legal & Compliance Department: compliance@eqwalgroup.com.
- In the event of a proven emergency: direct contact with the Group's General Counsel and Compliance Director.

8.3 Incident Management Procedure:

1. Receiving the alert.
2. Preliminary assessment of severity and risk by the Compliance Officer within 24 hours.
3. Immediate notification to the Group's Legal & Compliance Department if the alert is deemed **serious**.
4. Suspension of the relevant transaction or business relationship.
5. Internal investigation conducted by the Group's Legal & Compliance Department, assisted if necessary by external counsel.
6. Identification of corrective actions and implementation.
7. Evaluation of the obligation to notify the competent authorities (OFAC, Treasury Department, etc.).
8. Complete documentation of the incident and the measures taken, report
9. Review of procedures and update of controls as necessary.

Employees who have concerns about compliance with economic sanctions should report them immediately to their line manager or report their concerns to the Group's whistleblowing policy by contacting compliance@eqwalgroup.com.

No Employee will be subject to reprisal for reporting information about potential compliance issues in good faith. Any retaliation for reporting suspected misconduct or participating in an investigation should be immediately reported to the Company's General Counsel.

9. Enforcement

Employees who violate this Policy may be subject to disciplinary action up to and including termination of employment. If an Employee's conduct violates applicable economic sanctions, he or she may be subject to referral for prosecution. Violations of this Policy by third parties will be considered grounds for termination of the agreement and may result in referral for prosecution.

10. Review and Update of the Policy

This Policy will be reviewed from time to time by Eqwal Group's Legal & Compliance Department to take into account significant changes in the international regulatory framework for economic sanctions. An extraordinary review is triggered in the following situations:

- Significant evolution of the international regulatory framework for economic sanctions.
- Extension of the Group's activities to new geographic markets with a risk of sanctions.
- A major incident of non-compliance that revealed a gap in the existing system.
- Acquisition or integration of a new entity into the Group's scope, if applicable.
- Recommendation from an internal or external auditor.

ANNEX – REFERENCES

This annex gathers all the references (official sources, regulatory texts and guidance documents) cited in the Policy.

1. United Nations

UN Security Council Resolution 2664 (2022) (Global Humanitarian Exemption from Asset Freezes):
<https://main.un.org/securitycouncil/en/content/sres2664-2022>

2. European Union

European Commission Guidance – Humanitarian assistance in environments subject to EU sanctions:
<https://finance.ec.europa.eu/eu-and-world/sanctions-restrictive-measures/humanitarian-assistance-environments-subject-eu-sanctions>

Regulation (EU) 2023/2694 (introduction of humanitarian exemptions in sanctions regimes):
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R2694>

Official Communication of the Council of the EU (2024):
<https://www.consilium.europa.eu/en/press/press-releases/2024/02/19/humanitarian-action-eu-introduces-further-exception-to-sanctions/>

3. United States (OFAC)

OFAC FAQ – exceptions and licenses (including humanitarian):
<https://ofac.treasury.gov/faqs/4>

Implementation of Humanitarian Exemptions (General Licenses):
<https://home.treasury.gov/news/press-releases/jy1175>

OFAC Specially Designated Nationals List – Sanctions List Service:
<https://sanctionslist.ofac.treas.gov/Home/SdnList>

4. United Kingdom (OFSI / FCDO)

Official guidance – NGOs and sanctions:
<https://www.gov.uk/government/publications/financial-sanctions-guidance-for-charities-and-non-governmental-organisations-ngos>

Example of a General Humanitarian License (Syria):
<https://www.gov.uk/government/publications/ofsi-general-licence-int20255810196>

UK legal basis (transposition of Resolution 2664):
https://www.legislation.gov.uk/ukxi/2023/121/pdfs/ukxiem_20230121_en.pdf

5. Other sources

Dual-Use Items: EU & US Export Control Law – CASRAI:
<https://casrai.org/guides/dual-use-items>

CASRAI dictionary – ECCN determination process:
<https://casrai.org/dictionary/term/eccn-determination-process>

FAQs: Access to Health Care Supplies and “Dual Use” Items and Restrictions – PHR:
<https://phr.org/our-work/resources/faqs-access-to-health-care-supplies-and-dual-use-items-and-restrictions/>

FATF – Black and grey lists (embargoed or restricted countries):
<https://www.fatf-gafi.org/fr/countries/liste-noire-et-liste-gris.html>

6. Regulatory texts cited in the Policy

- Regulation (EU) 2017/745 on medical devices (Article 2(1))
- Regulation (EU) 2021/821 (dual-use items)
- UN Security Council Resolution 2664 (2022)
- Sanctions and Anti-Money Laundering Act 2018 (United Kingdom)
- Export Administration Regulations (EAR) – 15 C.F.R. Parts 730–774 (including Part 774, Supplement No. 4)
- International Traffic in Arms Regulations (ITAR) – 22 C.F.R. Parts 120–130
- 31 C.F.R. § 560.530 (Iran – medical devices) and 31 C.F.R. § 510.521 (North Korea – medical devices)