

## 1.0 Purpose

Align's Global Compliance and Ethics Program establishes the CLEAR framework for Conducting Legal, Ethical and Responsible business. It is how we turn our Global Code of Conduct, which is our commitment to ethical decision making and legal compliance, into action. Our Global Compliance and Ethics Program is designed to guide our organization and each of us so we can be CLEAR on how to implement applicable laws, regulations, industry standards, and best practices such as:

- U.S. Department of Health and Human Services, Office of Inspector General's Guidance for Pharmaceutical Manufacturers which includes medical device manufacturers.
- AdvaMed Code of Ethics on Interactions with Health Care Professionals
- MedTech Europe Code of Ethical Business Practice
- U.S. Department of Justice and the U.S. Securities and Exchange Commission's guidance, *A Resource Guide to the U.S. Foreign Corrupt Practices Act*
- U.S. Sentencing Guidelines
- U.S. Department of Justice guidance on Evaluating Corporate Compliance Programs
- U.K. Serious Fraud Office Guidance on Corporate Compliance
- California Health & Safety Code, Sections 119400-119402

## 2.0 Scope

Align's Compliance and Ethics Program applies to all of us at Align and our all our stakeholders who are invested in Align's committed to CLEAR.

## 3.0 CLEAR: Conducting Legal, Ethical and Responsible Business

### 3.1. Leadership Commitment to CLEAR

Our leadership is committed to conducting legal, ethical and responsible business; and they do so by making decisions consistent with our Code and by speaking to Align's commitment to integrity and compliance.

Our leaders:

- Oversee and implement the strategic direction and improvements to our compliance and ethics program to provide reasonable assurance to Align's Board of Directors that Align has the internal controls and framework needed to comply with applicable laws and regulations;
- Promote a culture of integrity and ethical decision making; and
- Oversee resolution of concerns, issues or questions on compliance and ethics matters.

Align's Global Compliance and Ethics team develops and provides reports, as it determines necessary, but not less frequently than once each fiscal quarter, to Align's Executive Management Committee and to Align's Audit Committee of the Board of Directors. These regular reports enable the EMC and the Audit Committee to provide strategic direction on Align's Global Compliance and Ethics Program so Align is accountable for conducting business with integrity and in compliance with laws.

The reports at a minimum shall include:

- Information on the operation and effectiveness of Align's Global Compliance and Ethics Program; and
- Information, to include resolution, on concerns, questions, issues and investigations relating to the Global Compliance and Ethics Program.

### 3.2. Risk Assessments

Align regularly conducts risk assessments to assess our risk of non-compliance with laws, regulations, industry standards and our Code. Our risk assessment methods are designed to identify both existing and emerging risks. We work to prioritize our highest risks and develop strategies to mitigate those risks consistent with Align's business strategies.

### 3.3. Policies and Procedures

Based on our risk profile and our business strategies, Align develops policies and procedures that provide us guidance so our business practices are ethical and comply with the law.

### 3.4. Training and Communications

Align develops and delivers trainings, communications and guidance on our Code and on our policies and procedures, to include annual certification on following our Code. Align develops and delivers country specific trainings, communications and guidance as needed.

### 3.5. Speaking Up

Align's Global Speak Up Policy requires that we each speak up, raise concerns, ask questions, and seek guidance and that we cooperate in any investigation related to our Code. The Global Speak Up Policy prohibits retaliation for speaking up and it provides avenues to speak up in person, electronically or anonymously.

### 3.6. Investigations

We investigate concerns and questions that those of us at Align or others have spoken up about. Align is committed to timely, thorough and objective investigations so that misconduct or internal control issues are identified and remediated.

### 3.7. Incentives and Discipline

When our Code, policies and procedures, the law or industry standards have been violated, we carry out appropriate discipline. In developing our personal career goals and objectives, we include ones that call upon us to be active participants in conducting legal and ethical business.

### 3.8. Holding Ourselves Accountable

We hold ourselves accountable for having effective compliance controls, communications, training, and culture. To do so, our Global and Regional Compliance and Ethics teams monitor our Global Compliance and Ethics Program to assure our program is agile, effective, and responsive.

### 3.9. Working with Third Parties

We work with our customers and business partners to assure they understand our commitment to complying with laws and to ethical decision-making. We are committed to conducting due diligence to hold our customers and business partners accountable for complying with laws and making ethical decisions.

## 4.0 Responsibility and Resources

Align's Corporate Compliance and Ethics Committee along with its Global and Regional Compliance and Ethics teams are responsible for implementing, improving and maintaining Align's Global Compliance and Ethics Program. Information on our program, our policies, procedures, training and other guidance is on Align's internal website, Smile Central. Questions about our Program or ideas to improve our Program should be directed to Align's Global Compliance and Ethics team or sent to [compliancehelp@aligntech.com](mailto:compliancehelp@aligntech.com).

## ALIGN DECLARATION OF COMPLIANCE

Align is committed to compliance and strives to maintain an active and effective compliance and ethics program. As part of Align's ongoing efforts to maintain legal compliance and an ethical culture, we have developed and implemented a Global Compliance and Ethics Program that is designed to comply with applicable laws as well as industry standards relating to the marketing and promotion of our products to health care professionals. To our knowledge, as of the date of this declaration, Align is in material compliance with its Global Compliance and Ethics Program, as described here, and with California Health & Safety Code, Sections 119400-119402.

A copy of this document may be obtained by calling 1-888-822-5446 or contacting [compliancehelp@aligntech.com](mailto:compliancehelp@aligntech.com).

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