REGULATORY STATEMENT

INTEGRA

Environmental and Material Compliance Regulations

INTEGRA Biosciences is committed to provide reliable, high quality products which are safe and environmental friendly – Compliance with relevant environmental legislation worldwide is an important part of **INTEGRA Biosciences** mission. **INTEGRA Biosciences** aims to minimize the environmental footprint of its products during the entire product life cycle.

Material compliance covers both environmental and human rights aspects during the entire life cycle of products starting with mining and ending with waste disposal or recycling.

This document explains how **INTEGRA Biosciences** complies with the following laws and regulations:

- The European Union (EU) Directive on "Restriction of use of certain Hazardous Substances in electrical and electronic equipment", 2011/65/EU **RoHS2** Directive, see 1
- The Management Methods for Restricted Use of Hazardous Substances in Electrical and Electronic Products (**China RoHS**), Order no 39, see 1
- The European Union (EU) Regulation EC 1907/2006 on Registration, Evaluation, Authorization and Restriction of Chemicals (**REACH** Regulation), see 2
- The European Union (EU) Directive on Waste Electrical and Electronic Equipment Directive, 2012/19/EU (**WEEE** Directive), see 3
- The California **Proposition 65**, formally titled: "The Safe Drinking Water and Toxic Enforcement Act of 1986", see 4
- The U.S. Act – Section 1502 of the **Dodd-Frank** Wall Street Reform and Consumer Protection Act of 2010, see 5
- The European Union (EU) Regulation 2017/821 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas (**EU conflict minerals regulation**), see 5

INTEGRA Biosciences monitors changes and applicability of the above regulations to ensure continued compliance and will update this document as required accordingly.

1 RoHS

RoHS stands for "**R**estriction **o**f **H**azardous **S**ubstances". Regulations with this title are known in several countries worldwide. The first regulation of this kind was introduced by the European Union in 2002, the current directive is **2011/65/EC** with amendments being made on a frequent basis (e.g. 4 in 2016, 13 in 2017 and 7 in 2018). Other similar regulations are known in e.g. **China (Order No 39), Turkey** and **the UAE**. The United Arab Emirates (UAE) is a member of the Gulf Cooperation Council (GCC), and within this framework, RoHS-like regulations have been developed to regulate the use of hazardous substances in electronic devices. These regulations are part of efforts to protect the environment and promote public health.
However, it is important to note that the exact requirements and implementation in the UAE may differ from those of the EU, even though the basic principles are similar. Compliance with these regulations is monitored by the relevant national and regional authorities to ensure that the regulations are followed and no hazardous substances are used in products.

The original RoHS regulation aimed to restrict six hazardous materials found in electrical and electronic products by setting maximum allowed levels for the following substances: **lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE).** Although allowed limits for the six base substances are the same, the regulations differ in declaration and marking requirements, exemptions and the amount of additional substances.
INTEGRA Biosciences compliance with RoHS regulations is found on the conformity declarations of the corresponding products. Conformity declarations are all available on our webpage Download Center |

INTEGRA, please use the filter option **Certificates** from the drop down list.

INTEGRA Biosciences continuously monitors the application scope of the current **RoHS regulations** together with its suppliers to ensure continued compliance and to update the corresponding statements accordingly.

2 REACH

The **REACH** (**R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals) Regulation (EC) No. 1907/2006 aims, among others, to enhance the level of protection of the human health and the environment from the use of chemicals. **E**uropean **CH**emical **A**gency (**ECHA**) continuously reviews substances that may have serious effects on the human health or the environment. Substances fulfilling one or more of the criteria defined in Article 57 of the **REACH** Regulation are identified as **S**ubstances of **V**ery **H**igh **C**oncern (**SVHC**) and put in the "Candidate List for Authorization". The list is regularly updated and published on the **ECHA website** (http://echa.europa.eu/candidate-list-table). The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorization procedure. One of the targets of the **REACH** regulation is to encourage industry to find new alternatives and substitute these substances for safer ones.

A part of **REACH** regulation applies to laboratory equipment and materials, which fall under the scope of "articles" and the corresponding requirements for substances in articles under the **REACH** Regulation. Authorization and restriction requirements do not only affect companies using substances for the production of articles but also downstream users in general. Each producer, supplier and importer of articles has to control and notify the presence of substances as defined in Article 57 of the **REACH** Regulation. Article 33 aims to ensure that sufficient information is communicated down the supply chain to allow safe use of the articles. In case a substance is in the Candidate List and is present in an article with a concentration higher than 0.1% by weight, it is the duty of each supplier in the supply chain of the article to provide sufficient information, at least the name of the substance, to downstream users.
Various non EU countries already have adopted or are currently in the process of adopting the **REACH** regulation in their national laws.

INTEGRA Biosciences, together with its suppliers, continuously reviews the application scope of the **REACH regulation** to ensure compliance, to provide supply chain information and to evaluate alternative substances whenever possible or required. **INTEGRA Biosciences** will continuously update Conformity declarations available on our webpage Download Center | INTEGRA, please use the filter option **Certificates** from the drop down list.

3 WEEE

The first edition of the **WEEE** directive 2002/96/EC was seen as failing to achieve some of its goals and was thus amended in 2011 to the current **2012/19/EU** edition. The main goal of the directive is to achieve a collection rate of 20 kg of **E**lectric and Electronic **E**quipment (EE) per year per capita. The regulation covers not only EE but also associated batteries and packaging material.

The **WEEE** directive is the blueprint with minimum requirements to be transposed into national regulations. These are legally binding for all players concerned. As with all European directives, national regulations may deviate from the directive as long as its minimum requirements are met.

The current **WEEE** regulation applies to all private and business use EE, it has a so called "open scope" starting from August 15, 2018. Only military use goods and incandescent light bulbs are exempted. Prior to 2018 further categories of goods, e.g. IVD were also exempted.

To comply with **WEEE** regulation all EE sold in the common market must be marked with the "wheeled bin" symbol.

INTEGRA Biosciences has marked all EE put on the market with the "wheeled bin" since the inception of the European **WEEE** regulation. In markets with direct sales by national subsidiaries, **INTEGRA Biosciences** subsidiaries are registered and also offer collection of electronic waste as participating members of collection schemes or they collect EE directly, depending on the local regulation.

4 Proposition 65

Proposition 65, formally known as the Safe Drinking Water and Toxic Enforcement Act of 1986, is a California state law. It requires the State of California to publish a list of chemicals known to cause cancer, birth defects or other reproductive harm. This list, which must be updated at least once a year, has grown to include about 900 chemicals since it was first published in 1987.
By law, listed chemicals must carry a warning to the end user unless exposure is so low as not to pose a significant risk of cancer or is well below levels observed to cause birth defects or other reproductive harm. If a warning is placed on a product label or posted or distributed in a workplace, business or rented dwelling, the entity issuing the warning knows or believes that it is exposing individuals to one or more listed chemicals.

INTEGRA Biosciences, together with its suppliers, continuously monitors components and strives to market products that are safe with respect to the listed substances, unless otherwise stated. The current list of chemicals can be found here: https://oehha.ca.gov/proposition-65/chemicals

5 Conflict Minerals

17 CFR PARTS 240 and **249b**, the so-called "**Dodd-Frank Wall Street Reform and Consumer Protection Act**" requires companies which are publicly listed to declare whether their products contain so-called 3TG (Tungsten, Titanium, Tantalum or Gold) Minerals from the Democratic Republic of Congo (formerly Zaire, not to be confused with Republic of the Congo).
The **European Union (EU) Regulation 2017/821** laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas targets the same sources and minerals as the **Dodd-Frank Wall Street Reform and Consumer Protection Act**.
The goal of both regulations is to reduce the income Congolese warlords generated from illegal mining operations, exploiting child and slave labor.

INTEGRA Biosciences does not directly source or process 3TG minerals.
3TG minerals are contained in **INTEGRA Biosciences** products in the form of solder, as part of electronic components, or in metal alloys. As part of reasonable due diligence, **INTEGRA Biosciences** requests declarations from its component suppliers in a regular interval to verify their continued compliance with the regulations.

Based on the information received, **INTEGRA Biosciences** declares that its products contain 3TG minerals sourced from conflict–free areas.

INTEGRA

6 Signature

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Urs Hartmann
CEO INTEGRA Biosciences AG

Daniela Gross
Head of Corporate Quality

If you require further information or a more detailed explanation on a specific aspect, please do not hesitate to contact us!

INTEGRA Biosciences AG
7205 Zizers, Switzerland
T +41 81 286 95 30
info@integra-biosciences.com

INTEGRA Biosciences Corp.
Hudson NH 03051, USA
T +1 603 578 5800
info-us@integra-biosciences.com

INTEGRA Biosciences Deutschland GmbH
35444 Biebertal, Deutschland
T +49 6409 81 999 15
info-de@integra-biosciences.com

INTEGRA Biosciences SAS
95062 Cergy-Pontoise Cedex 1, France
T +33 1 34 30 76 76
info-fr@integra-biosciences.com

INTEGRA Biosciences Ltd.
Thatcham Berkshire RG194EP, UK
T +44 1635 797 00
info-uk@integra-biosciences.com

INTEGRA Biosciences (Shanghai) Co., Ltd.
上海自由贸易试验区 201315, 中国
T +86 21 5844 7203
info-cn@integra-biosciences.com

INTEGRA Biosciences KK
ちよだーく、ときょ 101-0031、じゃぱん
T +81 3 5962 4936
info-jp@integra-biosciences.com

INTEGRA Biosciences Nordic ApS
2605 Brøndby, Denmark
T +45 3173 5373
orders-nordic@integra-biosciences.com

INTEGRA Biosciences Ireland Limited
Blanchardstown, Dublin 15, Ireland
T +44 1635 797000
info-ie@integra-biosciences.com

INTEGRA Biosciences Pty Ltd
Brendale QLD 4500, Australia
T +61 7 3497 5800
info-au@integra-biosciences.com

INTEGRA Biosciences Benelux B.V
4814 DB Breda, Netherlands
T +32 78 48 66 75
orders-benelux@integra-biosciences.com