

May 30, 2025

# Fighting Against Forced Labour & Child Labour in Supply Chains Act

## **Introduction**

This report is made in accordance with the requirements of The Fighting Against Forced Labour and Child Labour in Supply Chains Act (hereinafter referred to as the "Modern Slavery Act"). This report has been prepared by INO Therapeutics LLC, a subsidiary of Mallinckrodt plc ("Mallinckrodt" or "INO") in order to comply with the Modern Slavery Act and covers the fiscal year ended December 27, 2024 (FY24). INO Therapeutics LLC is incorporated in Delaware, United States, and does business as a Non-Resident Importer of Record located at 6345 Dixie Road, Unit 1, H9R 5H8, ON L7J 2E4. Mallinckrodt and its subsidiaries such as INO are committed to good corporate citizenship, the highest ethical standards, and do not tolerate any form of forced labour or child labour in our supply chains.

### **Business and Organizational Structure**

Mallinckrodt, our indirect parent company, is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Mallinckrodt operates our business in two reportable segments: Specialty Brands includes innovative specialty pharmaceutical brands and Specialty Generics includes specialty generic drugs and active pharmaceutical ingredients.

Within Canada, Mallinckrodt operates under its subsidiary, INO Therapeutics LLC, located at our Critical Care facility in Mississauga, Ontario.

INO Therapeutics manufactures INOmax<sup>®</sup> (nitric oxide) gas, a vasodilator indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents. The INOmax drug is wholly produced in our FDA-regulated Port Allen, Louisiana pharmaceutical manufacturing facility. The drug product is transferred into high-pressure gas cylinders for storage, transport and administering to patients.

INOmax must be administered using a calibrated, FDA-cleared Nitric Oxide Delivery System (NODS). Within Canada, NODS medical devices which are currently being utilized are INOmax<sup>®</sup> DSIR<sup>®</sup> Plus and INOmax DSIR Plus MRI. These medical devices are manufactured at our Madison, Wisconsin, United States, Critical Care facility. Mallinckrodt sources the components for these devices from suppliers located in North America, Europe, and Asia. As far as we are aware, based on our due diligence as described below, we do not source components from vendors that carry a particular risk of forced labour or child labour.



Both the drug product and NODS medical devices are imported into Canada and distributed to hospitals, clinics, medical facilities, and healthcare professionals where they are administered to patients. Once consumed, and at various intervals, the empty cylinders and NODS medical devices are returned to the US for refilling, repair, and/or recertification.

### **Policies**

People throughout the world count on Mallinckrodt products every day to help them lead healthier lives, and we believe that all human life should be held in the highest regard. While we believe the risk of modern slavery and human trafficking is relatively low in the highly regulated pharmaceutical industry, as a global company, Mallinckrodt recognizes that the responsibility to help ensure that modern slavery and human trafficking are not taking place extends to our business relationships as well. To support these efforts, we have joined the Pharmaceutical Supply Chain Initiative (PSCI), a consortium of pharmaceutical and healthcare companies that share a vision of better social, environmental and economic outcomes within the supply chain (https://pscinitiative.org/home).

Several steps have been taken to mitigate the risks associated with modern slavery in our business and supply chain. In particular, we support the human rights of our workers and the treatment of all people with dignity and respect through two core policy documents: **The Mallinckrodt Code of Conduct** and the **Mallinckrodt Supplier Code of Conduct**.

The **Mallinckrodt Supplier Code of Conduct** outlines the expectations for the ethical behavior of our suppliers and prohibits child and compulsory labour, human trafficking and slavery, unsafe and hazardous working conditions and environments, and any behavior that does not maintain human dignity and respect. These standards apply to all suppliers of goods and services to any Mallinckrodt business or supplier, regardless of location.

### **Supply Chain Due Diligence**

As part of compliance with U.S. SEC Conflict Minerals rules and aligned with our Conflict Minerals Policy, Mallinckrodt maps the supply chain of applicable suppliers, investigates potential risks, and implements mitigation activities, as appropriate.

A component of Mallinckrodt's Anti-Bribery and Anti-Corruption (ABAC) compliance program is to conduct due diligence on our upstream and downstream third parties, including customers, suppliers, vendors, and intermediaries. This process uses a risk-based approach to manage potential legal, financial and compliance risks linked to third parties representing us, including as to forced and child labour. Various screenings are also performed to include human trafficking, crimes against children, involvement in armed conflicts, grave violations against children in specific countries, checks against Interpol's databases and necessary checks to prevent forced labour under the Uyghur Forced Labor Prevention Act Entity List.



Additionally, Mallinckrodt voluntarily participates in the Customs-Trade Partnership Against Terrorism (C-TPAT) Program, which includes annual validations and risk assessments of suppliers outside of the U.S. to safeguard against threats including, human smuggling and forced labour of any kind.

#### **Training**

All of Mallinckrodt's employees are required to be trained on **The Mallinckrodt Code of Conduct** and to certify annually both to their understanding and compliance. Our Code reflects our aims for good global citizenship and worldwide social responsibility. It provides that we must provide clean and safe working environments and conditions free of human rights violations and forbids forced or child labour at Mallinckrodt and at the companies with which we work, with no exceptions. Our Code also prohibits human trafficking or slavery, unsafe or hazardous conditions or environments, or any behavior that does not maintain human dignity and respect. It further states that Mallinckrodt must not engage in activities that fail to protect individual dignity and respect, even if permissible under local law, and must pay a fair wage.

Disciplinary action may be taken against anyone found to have violated **The Mallinckrodt Code of Conduct** or the **Mallinckrodt Supplier Code of Conduct**, which can include termination of employment or supply agreements.

Mallinckrodt incorporates language related to compliance with the Act into certain contracts with suppliers and other service providers and will continue to assess appropriate incorporation of such language as business needs evolve. In addition, as a contractor to the U.S. government, we have specific obligations with regard to human trafficking pursuant to Federal Acquisition Regulation clause 52.222-50, Combating Trafficking in Persons, and Defense Federal Acquisition Regulation Supplement 252.222-7007, Representation Regarding Combating Trafficking in Persons. Mallinckrodt's Human Rights Position Statement that applies to all Mallinckrodt employees, subcontractors, suppliers and other third parties and expressly prohibits Mallinckrodt from engaging in child labor or forced, trafficked, or otherwise exploitative labor.

### Auditing and Reporting

Mallinckrodt encourages a Speak Up culture for reporting of any concerns through management, leadership, human resources, or Mallinckrodt's Compliance Integrity Hotline. Where available and permitted by law, the Integrity Hotline allows employees, vendors, suppliers, and other third parties to report concerns regarding any potential unethical situation or to get information or advice anonymously. The Integrity Hotline is available in Canada online via the web or via toll-free telephone number seven days a week, 24 hours a day. All good faith reports are investigated, and when necessary, corrective and/or



disciplinary action is taken to address the issue and prevent future occurrences, ensuring continuous adherence to legal and ethical standards.

Although we do not have a formal process for verifying our supply chains or obtaining certification of compliance from suppliers, all suppliers are subject to audit. Mallinckrodt conducts audits of its suppliers based on an internal assessment of business and environmental health and safety risk, and measures against recognized industry standards. We do not use a third party to verify supply chains or perform unannounced audits.

As of the date of this report, we have not identified any forced labour or child labour in our business or supply chain. Therefore, Mallinckrodt has not had to take any measures to remediate any forced labour or child labour or to remediate any loss of income to vulnerable families resulting from measures taken to eliminate the use of forced labour or child labour in our businesses or supply chains. We review and consider the sufficiency of our policies, practices and diligence protocols and assess whether any improvements in controls are needed.

#### **Approval and Attestation**

Pursuant to section 11(4)(a) [or subparagraph (b)(i) or subparagraph (b)(ii)], this report has been reviewed and approved by INO Therapeutic LLC's Board of Directors and signed by INO's President.

# INO THERAPEUTICS LLC

Bryan M. Keasons CO2F51BBBFC441B... Name: Bryan Reasons Title: President Date: May 30, 2025