

IBA Group (Ion Beam Applications Group)

Disclosure Report Date Submitted: April 18th, 2024



Disclosure Materials

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire that B Lab deems relevant for public stakeholders, then, as a condition of their certification, the company must:

- Be transparent about details of the disclosure issues identified on the company's public B Impact Report
- 2) Describe how the company has addressed this issue
- 3) Demonstrate that management practices are in place to avoid similar issues from arising in the future, when necessary.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit and integrity of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to a background check by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

B Lab's Public Complaints Process

Any party may submit a complaint about a current B Corp through B Lab's Public Complaint Process. Grounds for complaint include:

- Intentional misrepresentation of practices, policies, and/or claimed outcomes during the company's certification process
- Breaches of the B Corp Community's core values as expressed in our Declaration of Interdependence

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company.



Disclosure Questionnaire

Industries and Products

Yes No Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that **Animal Products or Services** $\boxed{}$ **Biodiversity Impacts** \square Chemicals \square **Disclosure Alcohol** \square **Disclosure Firearms Weapons** $\boxed{}$ **Disclosure Mining** $\boxed{}$ **Disclosure Pornography** $\boxed{}$ **Disclosure Tobacco** $\boxed{}$ **Energy and Emissions Intensive** $\boxed{}$ Industries Fossil fuels \square Gambling **Genetically Modified Organisms** $\overline{\mathbf{A}}$ Illegal Products or Subject to $\overline{\mathbf{A}}$ **Phase Out** Industries at Risk of Human \square **Rights Violations Monoculture Agriculture** \square Nuclear Power or Hazardous $\overline{\mathbf{A}}$ **Materials** Payday, Short Term, or High **Interest Lending Water Intensive Industries** $\overline{\mathbf{A}}$ Tax Advisory Services

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior		\checkmark
Breaches of Confidential Information		\checkmark
Bribery, Fraud, or Corruption		\checkmark
Company has filed for bankruptcy		\checkmark
Consumer Protection		V
Financial Reporting, Taxes, Investments, or Loans		N
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		V
Labor Issues		V
Large Scale Land Conversion, Acquisition, or Relocation		K
Litigation or Arbitration		V
On-Site Fatality		V
Penalties Assessed For Environmental Issues		V
Political Contributions or International Affairs		N
Recalls	V	
Significant Layoffs		V
Violation of Indigenous Peoples Rights		V
Other		\checkmark



Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing		\checkmark
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		V
Company prohibits freedom of association/collective bargaining		✓
Company workers are prisoners		\checkmark
Conduct Business in Conflict Zones	V	
Confirmation of Right to Work		\checkmark
Does not transparently report corporate financials to government		\vee
Employs Individuals on Zero-Hour Contracts		\vee
Facilities located in sensitive ecosystems		V
ID Cards Withheld or Penalties for Resignation		V
No formal Registration Under Domestic Regulations		\checkmark
No signed employment contracts for all workers		V
Overtime For Hourly Workers Is Compulsory		V
Payslips not provided to show wage calculation and deductions		\checkmark

	Yes	No
Sale of Data		K
Tax Reduction Through Corporate Shells		V
Workers cannot leave site during non-working hours		\searrow
Workers not Provided Clean Drinking Water or Toilets		\searrow
Workers paid below minimum wage		K
Workers Under Bond		K
Other		V

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones		V
Child or Forced Labor		\checkmark
Negative Environmental Impact		✓
Negative Social Impact		V
Other		V



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	January 2019; July and August 2020; July and September 2021; January, March and May 2022; November 2023.
Topic	Recalls due to corrections
Summary of Issue	IBA Group (Ion Beam Applications Group) supplies equipment and services in the field of proton therapy for the diagnosis and treatment of cancer and other illnesses. IBA is also specializing in the fields of industrial sterilization, radiopharmaceuticals and dosimetry solutions. Per the FDA or CE marking standards (regulatory agencies related to IBA fields of activity), for IBA devices, the recalls do not correspond to removing the device from the market but correspond to the deployment of corrections. Over the last 5 years, the company has had 9 recalls considered ""corrections"" done on the same product
	line the Proteus235- Proton Therapy System. Rather than recalling the product in its entirety, the instruments at risk of harming patients were updated to remove any risk of potential harm to patients.
	Detailed reasons for corrections are publicly detailed in the FDA Database IBA for each recall (under the Report section)."
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	Currently, IBA has released 38 ProtonTherapy Centers, called units by the FDA and 37 out of these 38 units have been impacted by at least one of these recalls over the last 5 years.
	These corrections represented 6% of the company's overall production across all products.
Impact on Stakeholders	FDA classified the recalls as a Class II, a situation in which use of or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
	No injuries were reported. Potential risks: mistreatment.
Management Practices	The actions, practices or policies implemented as a result of 'recalls' vary and are detailed in the referred FDA link, for any instance, under 'Action'. These actions are akin to 'Correction and Removal' or 'Field Safety Correction Action' in Europe. Recalls are a standard procedure necessitated by the complexity of products and the regulatory framework. They play a crucial role in enhancing products and testing procedures by providing opportunities for improvement and refinement: each corrective action serves as an opportunity to strengthen products, production and testing procedures, training and communication processes with customers as found appropriate.
Report	FDA Database IBA



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Operations located in Conflict Zones

Topic	Company has Operations in Russia
Summary of Issue	IBA Group (Ion Beam Applications Group) supplies equipment and services in the field of proton therapy for the diagnosis and treatment of cancer and other illnesses. The company has maintained the operation of a subsidiary in Russia (Dimitrovgrad) that operates as a proton therapy center (including treatment room). All employees currently working at the center are Russian nationals. Due to the Russia and Belarus Moratorium, B Lab requires that Certified B Corps to disclose (1) the company's current operations in Russia and/or Belarus, and (2) the company's human rights due diligence policies and practices.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	In FY23, 1% of the company's revenue was from operations in Russia.
Impact on Stakeholders	Business activities located in conflict zones are considered high-risk as they are more likely to cause or contribute to the conflict and/or sociopolitical instability. Countries classified as conflict zones are more likely to have a weak rule-of-law or a corrupt judicial system, which could undermine the effectiveness of operational grievance mechanisms for these businesses and their suppliers. In addition, the safety of the company's workers and other potential human rights violations are at risk.
Management Practices	IBA Group (Ion Beam Applications Group) has maintained its subsidiary in Russia to ensure the operation and maintenance of the proton therapy center in Dimitrovgrad. IBA operates in full compliance with the sanctions issued by the European Union. Without IBA assistance the proton therapy center cannot operate, which could have negative consequences for cancer patients. All employees currently working at the center are Russian nationals The company supports them both financially and with regards to the situation in Russia. None of their employees have been drafted so far, and the company can claim an exception for them in case this happens, considering their work in critical medical services.



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Disclosure Nuclear Power or Hazardous Materials

Issue Date	Ongoing
Topic	IBA Group provides equipment and services in the field of proton therapy, for the diagnosis and treatment of cancer.
Summary of Issue	The company generates hazardous waste related to its production activities, such as: - pieces of equipment that become radioactive over time as a result of interaction with ion beams during the production and testing of particle accelerators; - gloves, masks, protection suits contaminated during maintenance activities.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The company has generated 89 kg of hazardous waste in the 38 years of operations.
Impact on Stakeholders	Environmental impact due to radioactive waste disposition and contamination risk.
Management Practices	The company disposes all the hazardous waste with oversight and compliance of the authority responsible for radioactive wastes (ONDRAF). IBA Group is classified by ONDRAF as PPNC "small producer" due to small quantities of waste produced.