Certified B Corporation
bcorporation.net

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 and B Lab deems them to be material, the company must:

1) Be transparent about 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 systems are in place to avoid similar issues from arising in the future.

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

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to background checks 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.

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

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DISCLOSURE QUESTIONNAIRE

Company Name: Chiesi Group Date
Submitted: September 16, 2022

Industries & Products	Yes	No
Please indicate if the company is involved in production of or trade in any the following. Select Yes for all options that apply.		
Animal Products or Services		√
Biodiversity Impacts		√
Chemicals	√	More Details >>
Company Explanation Of Disclosure Item Flags		√
Disclosure Alcohol		√
Disclosure Firearms Weapons		√
Disclosure Mining		√
Disclosure Pornography		√
Disclosure Tobacco		√
Energy and Emissions Intensive Industries		√
Fossil fuels		√
Gambling		√
Genetically Modified Organisms		√
Illegal Products or Subject to Phase Out		√
Industries at Risk of Human Rights Violations		√
Monoculture Agriculture		√
Nuclear Power or Hazardous Materials		√
Payday, Short Term, or High Interest Lending		√
Water Intensive Industries		√
Tax Advisory Services		√

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		√
Child or Forced Labor		√
Negative Environmental Impact		√
Negative Social Impact		√
Other		√

Outcomes & Penalties	True	False
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		√
Breaches of Confidential Information		√
Bribery, Fraud, or Corruption		√
Company Explanation Of Disclosure Item Flags		√
Company has filed for bankruptcy		√
Consumer Protection		√
Financial Reporting, Taxes, Investments, or Loans		√
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		√
Labor Issues		√
Large Scale Land Conversion, Acquisition, or Relocation		√
Litigation or Arbitration	√	More Details >>
On-Site Fatality		√
Penalties Assessed For Environmental Issues		√
Political Contributions or International Affairs		√
Recalls	√	More Details >>
Significant Layoffs		√
Violation of Indigenous Peoples Rights		√
Other		√

Practices	True	False
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		√
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		√
Company Explanation Of Disclosure Item Flags		√
Company prohibits freedom of association/collective bargaining		√
Company workers are prisoners		√
Conduct Business in Conflict Zones		√
Confirmation of Right to Work		√
Does not transparently report corporate financials to government		√
Employs Individuals on Zero-Hour Contracts		√
Facilities located in sensitive ecosystems		√
ID Cards Withheld or Penalties for Resignation		√
No formal Registration Under Domestic Regulations		√
No signed employment contracts for all workers		√
Overtime For Hourly Workers Is Compulsory		√
Payslips not provided to show wage calculation and deductions		√
Sale of Data		√
Tax Reduction Through Corporate Shells		√
Workers cannot leave site during non-working hours		√
Workers not Provided Clean Drinking Water or Toilets		√
Workers paid below minimum wage		√
Workers Under Bond		√
Other		√

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY: Chiesi Group UPDATED AS OF: September 16, 2022

DISCLOSURE QUESTIONNAIRE CATEGORY	Industries reliant on chemicals
TOPIC	Chiesei manufactures and sells pharmaceutical products based on chemical inputs
SUMMARY OF ISSUE	Chiesi, as part of the pharmaceutical industry, is involved in the use of many chemicals, both during the production phase and during the research and development of new therapeutic solutions.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	More than 80% of Chiesi's products derive from chemically synthesized Active Pharmaceutical ingredients or contain chemical inputs.
IMPACT ON STAKEHOLDERS	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects to the environment and potential negative health impacts to workers exposed to chemical ingredients. In the last five years, Chiesi has not experienced any significant incidents or fine occurred related to environmental or worker impacts due to chemical use.
IMPLEMENTED MGT PRACTICES	"All Accidents and near misses are recorded according to the company's HSE (Health, Safety and Environment) certified Management System (ISO14001 and ISO45001) and are available on request. Chiesi adopted a Sustainable Chemistry policy, where a mitigation strategy is described in regards to substances responsible for climate change and management of substances of concern. Chiesi has developed a project named Life Cycle Perspective Tool (LCP), a systematic approach to environmental management that provides information to build knowledge about the life cycle of research, development, and production processes. Selection of less impacting materials (including raw materials, active pharmaceutical ingredients, process auxiliaries, and solvents) and quantitative evaluation according to the American Chemical Society Green Chemistry institute's established metrics for chemical processes under development are within the pillars of the project. The broader framework of the ""Eco-Friendly Products"" corporate project (where the LCP tool is included) is evaluating and will develop methods and metrics for comparison/benchmarks with other companies in the industrial sector. The project is currently under development. Chiesi acts as a Downstream User (DU) in compliance with the REACH regulation. Chiesi has an internal procedure that describes in detail how Chiesi approaches Substances of Very High Concern (SVHCs). Any new potential CMR (Carcinogenic, Mutagenic, or toxic for Reproduction), SVHC, PBTs (Toxic, Bioaccumulative or Persistent) substance, Endocrine disruptor, and Substance known to cause asthma is assessed during the LCP evaluation of the products under development and avoided whenever possible, or at least good Health Safety and Environment (HSE) and containment practices are in place. In an internal statement, Chiesi explains its position and strategy on the management of manufacturing effluents through monitoring, controlling, and minimizing the potential release of pharmaceutical ingredients in the environment (Pharmaceuticals in the Environment – PIE), in line with European Federation of Pharmaceutical Industries and Association (EFPIA) guidelines on PIE."
REPORT	"Chiesi's Sustainable Chemistry policy is available here: https://www.chiesi.com/en/processes/environment/ https://www.chiesi.com/flipbook.php?url=https://www.chiesi.com/documenti/149_sustainable-chemistry-policy.pdf "

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY: Chiesi Group

UPDATED AS OF: September 16, 2022

DISCLOSURE QUESTIONNAIRE CATEGORY	Recalls
ISSUE DATE	2019, January 2020, June 2022 - July 2022
TOPIC	Recalls due to product inconsistency, unsealed product and quality defects related to manufacturing issues
SUMMARY OF ISSUE	"In the last 5 years, Chiesi has recalled products in three different occasions. In 2019, an annual stability lot of Zyflo CR had an out of specification result at the 6 month timepoint for dissolution. In January 2020, Chiesi Group was notified of a potential issue on two LISAcath® samples that appeared to have the tip of the catheter partially or completely unsealed. Chiesi recalled all the batches that could present such defect as a precautionary measure. In June 2022 following a routine quality check performed by Chiesi it was noted that some catheters belonging to specific batches present a quality defect. This defect has not caused any adverse events but could be potentially harmful to the premature babies for whom LISAcath® is intended."
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	"In the Zyflo recall, 1 manufactured lot (2 packaged lots) were included in the recall. This lot represented 25% of the units released in 2019 and 3% of the units over the last 5 years. Related to LISACath 2020 recall, a total of 48 batches were recalled in 19 different countries. Units reconciliated from the recall were in total about 5000. All recalled packs were completely destroyed. About Lisacath recall 2022, a total of 12 markets were involved and to date 9 marktes completed the LISAcath units recall for a total of about 2900 units. The recall is still on going. The estimated cost of the recalls was € 319,779.00. "
IMPACT ON STAKEHOLDERS	"In the case of 2019, a health hazard assessment was performed and it was found to be highly unlikely that a slightly faster release profile seen in the annual stability lot would be identified by patients or would pose any risk. No related product complaints were received. FDA classified the recall 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. In the case of 2020, unsealed products represented a potential risk to the patient population of neonates for which LISAcath is intended to be used. No actual harm was reported and the problem was identified by physicians before using the product. For the 2022 LisaCath recall, the quality defect linked to manufacturing issues has not caused any adverse events but could be potentially harmful to the premature baby population for whom LISAcath® is intended. Despite only a limited number of faulty catheters being identified, Chiesi has issued the recall of all the impacted batches as a precautionary measure to avoid any potential risk to the fragile patient population of neonates for which LISAcath® is intended."
RESOLUTION	"In the product inconsistency case, Chiesi USA submitted a Changes Being Effected in 30 days supplement in June 2019 to add SkyePharma as an alternate testing laboratory for final release and stability testing. Regarding the 2020 case of recalls, the recall was a precautionary measure to avoid any potential risk to patients since only 2 catheters with the tip defect had been identified. The report of the 2022 investigation showed Chiesi is unable to guarantee the quality and provision of the LISAcath® catheter, due to recurrent manufacturing issues encountered by our third-party manufacturer of the device. As the quality of the catheter cannot be assured, Chiesi has requested of the relevant certifying body to remove LISAcath's CE certification. This implies a full recall of all catheters already distributed and a stop to all LISAcath® marketing and commercialisation of activities. This zero-risk approach reflects Chiesi's values of putting the patient at the centre of everything we do."
IMPLEMENTED MGT PRACTICES	"Chiesi in collaboration with the manufacturer investigated the issue of LISAcath recall. The investigation lead to an identification of the most probable root cause. As a consequence an appropriate CAPA (Corrective Action, Preventive Action) plan was implemented to avoid the reoccurrence of that specific issue related to the tipping detach. 2022 recall: Chiesi has immediately launched an internal investigation involving the manufacturer of the device to identify the root cause of the issue and evaluate potential impact on patient safety, while the manufacturer has temporarily put on hold the production of LISAcath®, until the root cause of the manufacturing issue is fully analized and reported to Chiesi Group. The analysis of the results of the internal investigation, Chiesi is unable to guarantee the quality and provision of the LISAcath® catheter, due to recurrent manufacturing issues encountered by our third-party manufacturer of the device. As the quality of the catheter cannot be assured, Chiesi has requested of the relevant certifying body to remove LISAcath's CE certification. This implies a full recall of all catheters already distributed and a stop to all LISAcath® marketing and commercialisation of activities. Regarding Zyflo's recall, the root cause of the investigation was determined to be known variability between the dissolution methods (automated method vs manual method) used at the testing laboratories at SkyPharma (performs core tablet manufacturing) and Patheon (performs tablet coating and packaging). To eliminate the variability of dissolution testing results between the two labs (which was the cause of the out of specification result), Chiesi submitted a Changes Being Effected in 30 days supplement to FDA which added SkyePharma as an alternate testing laboratory for release and stability testing for Zyflo CR/Zileuton ER tablets. Based on the comparative dissolution study results, Chiesi has subsequently moved all release and stability testing to SkyPharma. Since this change was made, there have been no additional out of specification results for dissolution. Due the root cause being laboratory/method based, no subsequent manufacturing changes were made."
RELATED INCIDENTS (YES/ NO)	Yes, two of the recalls involved the same product.

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PROVIDED BY: Chiesi Group UPDATED AS OF: September 16, 2022

DISCLOSURE QUESTIONNAIRE CATEGORY	Litigation and Arbitration
ISSUE DATE	Ongoing
TOPIC	Labor Litigation
SUMMARY OF ISSUE	66 cases of labor arbitration against the company were identified in the last 5 years in Brazil. Of those, 31 cases are closed and 35 are still pending.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	"The total amount paid in the settled cases was of R$ 270,000.00 and the amount paid to plaintiff in partially in favor cases was of R$ 96,000.00 The total expected payout in pending lawsuits is approximately R$5.6 million. The company has 35 pending cases which, compared to a total base of 359 employees in Brazil, yield a 9.7% litigation rate."
IMPACT ON STAKEHOLDERS	Labor suits involve a range of actions filed by former employees relating to, among other things, overtime, additional wages and severance payment.
IMPLEMENTED MGT PRACTICES	"In order to reduce the number of labor lawsuits, Chiesi Farmaceutica LTDA has adopted the following practices: - Training on team management for the Field Force; - Evaluation of labor regularity certificates from outsourced companies; - Outsourced companies' supplier qualifications; - Assessment of legal risks in the practices adopted by the company; - Adoption of best practices in time management of hours in Field Force."
RESOLUTION	Of the 31 closed cases, 2 were settled with payment, 3 were in favor of the company, and 4 were partially in favor. The remaining cases relates to outsourced employees in which Chiesi has a subsidiary responsibility.
RELATED INCIDENTS (YES/ NO)	All 66 cases are related.