
The Federal Trade Commission (“FTC”), having reason to believe that Ortho-Clinical Diagnostics, Inc., a corporation, has violated the Federal Trade Commission Act (“FTC Act”), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Ortho-Clinical Diagnostics, Inc., is a New York corporation with its principal office or place of business at 1001 US Route 202, Raritan, NJ 08869.
2. Respondent provides medical device and in vitro diagnostics services.
3. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.
4. Respondent has set forth by the U.S. government and the European Commission.

Privacy Shield

5. The EU-U.S. Privacy Shield framework (“Privacy Shield”) was designed by the U.S. Department of Commerce (“Commerce”) and the European Commission to provide a mechanism for U.S. companies to transfer personal data outside of the EU that is consistent with the requirements of the European Union Directive on Data Protection. Enacted in 1995, the Directive sets forth EU requirements for privacy and the protection of personal data.

Among other things, it requires EU Member States to implement legislation that prohibits the transfer of personal data outside the EU, with exceptions, unless the European Commission has made a determination that the recipient jurisdiction's laws ensure the protection of such personal data. This determination is referred to commonly as meeting the EU's "adequacy" standard.

6. To satisfy the EU adequacy standard for certain commercial transfers, Commerce and the European Commission negotiated the EU-U.S. Privacy Shield framework, which went into effect in July 2016. The EU-U.S. Privacy Shield framework allows companies to transfer personal data lawfully from the EU to the United States. To join the EU-U.S. Privacy Shield framework, a company must self-certify to Commerce that it complies with the Privacy Shield Principles and related requirements that have been deemed to meet the EU's adequacy standard. Any company that voluntarily withdraws or lets its self-certification lapse must take steps to affirm to Commerce that it is continuing to protect the personal information it received while it participated in the program or delete or return the data collected. Companies must also respond promptly to inquiries and other requests for information from Commerce relating to the company's adherence to the Privacy Shield Principles.
7. Companies under the jurisdiction of the FTC, as well as the U.S. Department of Transportation, are eligible to join the EU-U.S. Privacy Shield framework. A company under the FTC's jurisdiction that claims it has self-certified to the Privacy Shield Principles, but failed to self-certify to Commerce, or failed to comply with the Privacy Shield Principles, may be subject to an enforcement action based on the FTC's deception authority under Section 5 of the FTC Act.
8. Commerce maintains a public website, <https://www.privacyshield.gov/welcome>, where it posts the names of companies that have self-certified to the EU-U.S. Privacy Shield framework. The listing of companies, <https://www.privacyshield.gov/list>, indicates whether the company's self-certification is current.
9. Respondent has disseminated or caused to be disseminated privacy policies and statements on the <https://www.orthoclinicaldiagnostics.com/en-us/home/privacy-policy> website, including, but not limited to, the following statements:

EU-U.S. Privacy Shield

Ortho-Clinical Diagnostics, Inc. (and its parent/subsidiary company, Ortho-Clinical Diagnostics Bermuda Co. Ltd.) participates in and has certified its compliance with the EU-U.S. Privacy Shield Framework and the Swiss-U.S. Privacy Shield Framework. Ortho-Clinical Diagnostics, Inc. is committed to subjecting all personal data received from the European Union (EU) member countries and Switzerland, respectively, in reliance on each Privacy Shield Framework, to the F1 (hi)-2 1 (ub(o)2 (s)1 (tic))-1 (.d)]TJoltid, rFriotnd, rir

10. Although Respondent obtained Privacy Shield certification in April 2017, that certification lapsed one year later, in 2018.
11. In August 2018, Commerce warned the company to take down its claims that it participated in Privacy Shield unless and until such time as it completed the recertification process. Respondent did not do so. While Respondent retained data it collected while it participated in Privacy Shield, it did not withdraw and affirm its commitment to protect such data.
12. After allowing its certification to lapse, Respondent continued to claim, as indicated in paragraph 9, that it participated in the EU-U.S. Privacy Shield framework.
13. The Privacy Shield Principles include Supplemental Principle 7, which requires any company that participates in Privacy Shield to verify, at least once a year, through self-assessment or outside compliance review, that the assertions it makes about its Privacy Shield privacy practices are true and that those privacy practices have been implemented. The verification statement must be signed by a corporate officer or the outside reviewer and is required to be made available on request to the FTC or Department of Transportation, whoever has unfair and deceptive practices jurisdiction over the company.
14. Respondent is under the jurisdiction of the FTC. During the 2017-18 period that Respondent was certified to participate in Privacy Shield, Respondent failed to comply with the requirement to obtain, through self-assessment or outside compliance review, an attested verification statement that the assertions it had made about its Privacy Shield privacy practices during the time it participated in the program were true and that those privacy practices had been implemented. Respondent failed to provide its attested verification statement to the FTC.

Count 1—Privacy Misrepresentation

15. As described in Paragraph 9, Respondent represented, directly or indirectly, expressly or by implication, that it is a current participant in the EU-U.S Privacy Shield framework.
16. In fact, as described in Paragraphs 10-12, Respondent was not a current participant in the EU-U.S. Privacy Shield framework in 2018 and 2019. Respondent's certification lapsed in 2018, and it was not renewed. Therefore, the representation set forth in Paragraph 15 is false or misleading.

Count 2—Misrepresentation Regarding Verification

17. As described in Paragraph 9, Respondent represented that it complied with the EU-U.S. Privacy Shield framework principles.

18. In fact, as described in Paragraphs 13-14, Respondent did not comply with the EU-U.S. Privacy Shield framework principles. In particular, it failed to comply with the verification requirement in Privacy Shield Supplemental Principle 7. Therefore, the representation set forth in Paragraph 17 is false or misleading.

Count 3—Misrepresentation Regarding Continuing Obligations

19. As described in Paragraph 9, Respondent represented that it complied with the EU-U.S. Privacy Shield framework principles.

20. In fact, as described in Paragraph 11, Respondent has not affirmed to Commerce that it will continue to apply the principles to personal information that it received during the time it participated in the program. Therefore, the representation set forth in Paragraph 19 is false or misleading.

Violations of Section 5 of the FTC Act

19. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or

— - —