

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF DAKOTA

FIRST JUDICIAL DISTRICT

Susan Krause,

Case Type: Employment

Plaintiff,

Court File No.: _____

Judge: _____

v.

SUMMONS

Integra LifeSciences Corporation,

Defendant.

THIS SUMMONS IS DIRECTED TO THE ABOVE-NAMED DEFENDANT:

1. **YOU ARE BEING SUED.** The Plaintiff has started a lawsuit against you. The *Complaint* is attached to this *Summons*. Do not throw these papers away. They are official papers that start a lawsuit and affect your legal rights, even if nothing has been filed with the court and even if there is no court file number on this *Summons*.

2. **YOU MUST REPLY WITHIN 21 DAYS TO PROTECT YOUR RIGHTS.** Your reply is called an *Answer*. Getting your reply to the Plaintiff is called service. You must serve a copy of your *Answer* or *Answer and Counterclaim* (Answer) within 21 days from the date you received the *Summons* and *Complaint*. You can find the *Answer* form and instructions on the MN Judicial Branch website at www.mncourts.gov/forms under the "Civil" category. The instructions will explain in detail how to fill out the *Answer* form.

3. **YOU MUST RESPOND TO EACH CLAIM.** The *Answer* is your written response to the Plaintiff's *Complaint*. In your *Answer* you must state whether you agree or disagree with each paragraph of the *Complaint*. If you think the Plaintiff should not be given everything they asked for in the *Complaint*, you must say that in your *Answer*.

4. **YOU WILL LOSE YOUR CASE IF YOU DO NOT SEND A WRITTEN RESPONSE TO THE COMPLAINT TO THE PERSON WHO SIGNED THIS SUMMONS.** If you do not serve a written *Answer* within 21 days, you may lose this case by default. You will not get to tell your side of the story. If you choose not to respond, the Plaintiff may be awarded everything they asked for in their *Complaint*. If you agree with the claims stated in the *Complaint*, you don't need to respond. A default judgment can then be entered against you for what the Plaintiff asked for in the *Complaint*. To protect your rights, you must serve a copy of your *Answer* on the person who signed this *Summons* in person or by mail at this address: Meagher & Geer, 33 South Sixth Street, Suite 4300, Minneapolis, MN 55402.

5. **LEGAL ASSISTANCE.** You may wish to get legal help from an attorney. If you do not have an attorney and would like legal help: visit www.mncourts.gov/selfhelp and click on the "Legal Advice Clinics" tab to get more information about legal clinics in each Minnesota county or Court Administration may have information about places where you can get legal assistance. **Even if you cannot get legal help, you must still serve a written *Answer* to protect your rights or you may lose the case.**

6. **ALTERNATIVE DISPUTE RESOLUTION (ADR).** The parties may agree to or be ordered to participate in an ADR process under Rule 114 of the Minnesota Rules of Practice. You must still serve your written *Answer*, even if you expect to use ADR.

Dated: November 8, 2024

By: /s/ Jonathan D. Miller

Jonathan D. Miller (#292485)
Debra L. Weiss (#288810)
Anthony W. Joyce (#0400823)
Meagher + Geer, P.L.L.P.
33 South Sixth Street, Suite 4300
Minneapolis, MN 55402
(612) 338-0661
jmiller@meagher.com
dweiss@meagher.com
ajoyce@meagher.com

Attorneys for Plaintiff Susan Krause

ACKNOWLEDGMENT

The undersigned hereby acknowledges that costs, disbursements and reasonable attorney and witness fees may be awarded pursuant to Minn. Stat. §549.211 to the party against whom the allegations in this pleading are asserted.

Dated: November 8, 2024

/s/ Jonathan D. Miller

Jonathan D. Miller (#292485)
Debra L. Weiss (#288810)
Anthony W. Joyce (#0400823)

STATE OF MINNESOTA

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v.

COMPLAINT

Integra LifeSciences Corporation,

Defendant.

For her Complaint against Defendant Integra LifeSciences Corporation (“Integra”), Plaintiff Susan Krause (“Plaintiff”) states as follows:

PARTIES

1. Plaintiff is an individual who resides at 3885 154th Street W., Rosemount, Minnesota 55068.

2. Integra is a Delaware Corporation with its principal place of business located at 1100 Campus Road, Princeton, New Jersey 08540, and with its Minnesota registered office located at 2780 Snelling Avenue North, Suite 101, Roseville, Minnesota 55113.

JURISDICTION AND VENUE

3. This Court has subject-matter jurisdiction over this action pursuant to Minnesota Statutes § 484.01, subd. 1, because this Court has general jurisdiction over the types of claims asserted in this action.

4. This Court has personal jurisdiction over Integra because Plaintiff was an employee of Integra’s who physically worked in Minnesota. Plaintiff signed the employment offer in Minnesota. Integra stated in the signed employment offer that Plaintiff was not required to relocate for her position. Integra’s paychecks to Plaintiff were sent to Minnesota, and Plaintiff paid

Minnesota income tax. Integra has additional employees who resided in and worked remotely within the State of Minnesota, including members of Plaintiff's team. Additionally, Integra is a national company doing business in Minnesota with its products being marketed and sold in Minnesota. Integra is aware that its products are sold to businesses and hospitals in the State of Minnesota, including but not limited to Mayo Clinic located in Rochester, Minnesota and Children's Hospital Association, Inc., for use in patients located in the State of Minnesota. Integra maintains a registered office in the State of Minnesota.

5. Venue is proper in this judicial district pursuant to Minnesota Statutes § 542.09 because the causes of action arose in this district. Plaintiff was employed remotely by Integra in this district, the unlawful employment practices were committed in this district, and Plaintiff would have continued to work in this district but for the alleged unlawful employment practices.

FACTUAL ALLEGATIONS

6. Plaintiff is an accomplished quality control leader with over 34 years of global leadership in quality, operations, compliance, design assurance, and business continuity. She has extensive Quality Management System leadership experience across industries and with medical device regulations. She holds a Bachelor of Science in Business Management from Northwestern College and a Master of Arts in Organizational Leadership from Bethel College.

7. Plaintiff was employed at Integra from June 21, 2021, to March 11, 2024, as Integra's Corporate Vice President and Chief Quality Officer ("CQO") until she was forced to resign due to illegal, discriminatory, and retaliatory treatment by Integra.

8. Integra is a global medical technology company that develops, manufactures, and sells medical products, including regenerative tissue technologies and neurological solutions.

9. Jan De Witte is the Chief Executive Officer (“CEO” or “Mr. De Witte”) of Integra, and Mr. De Witte was the CEO at all times relevant to this lawsuit.

10. Eric Schwartz was the Chief Legal Officer (“CLO” or “Mr. Schwartz”) of Integra at all times relevant to this lawsuit.

11. When Plaintiff began to work for Integra in June 2021, she took over the 600-person Quality organization, overseeing the quality of over 25,000 different products manufactured at over a dozen sites. She established new, more effective processes and addressed leadership issues at all sites.

12. [REDACTED]

13. [REDACTED]

14. Integra's Boston, Massachusetts location manufactures various products comprised primarily of bovine collagen from cow hides with intended uses in reconstructive surgeries and the treatment of burn victims and patients with skin damage.

15. Shortly after starting her position in June 2021, Plaintiff was made aware that Integra's Boston, Massachusetts location was expecting an FDA inspection within 90 days. Prior to accepting her position as the CQO, Plaintiff was told that Integra had finished remediating a quality issue in Boston and believed that the required FDA follow-up inspection would officially remove a 2019 Warning Letter and would allow Integra to submit a Surgimend Breast Reconstruction Pre-Market Approval ("PMA"), if the removal of the FDA 2019 Warning Letter had been successful.

16. In August 2021, Integra submitted the PMA of Surgimend Breast Reconstruction to the FDA. The open FDA warning letter had not yet been removed, but Integra went forward with submitting the PMA anyway because it believed at the time that the FDA warning letter would be removed within 60 days.

17. An extensive FDA inspection took place at the Integra Lifesciences TEI Biosciences facility in Boston from October 28, 2021, through November 12, 2021, which resulted in 483 adverse findings being issued. Due to the seriousness of these repeat findings, the FDA mandated that a regulatory meeting be held. That meeting was held on January 26, 2022, and Integra was required to develop a solid remediation plan or it would be issued further action in the form of a warning letter or consent decree.

18. As CQO, Plaintiff worked exhaustively without any vacation time through the Christmas/New Year's 2021 holiday to address the findings and keep the Boston facility running

and shipping product, even though male employees of Integra who could have assisted Plaintiff with that work were given vacation time.

19. Plaintiff attended a Senior Management Team meeting in Florida starting on March 5, 2022, where the CEO and the CLO [REDACTED]. As a result, Plaintiff went to the emergency room in Miami, Florida on March 8, 2022 because of dangerously high blood pressure, and returned to Minnesota on March 9, 2022 for further medical testing and medical treatment including the prescription of high blood pressure medication.

20. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21. On August 14, 2022, Plaintiff went to the emergency room and was diagnosed with COVID-19. Despite that serious condition, she was required by the CEO to continue working.

22. In August 2022, Integra was required by the FDA to issue a recall of its product, Cerelink, which monitors intracranial pressure during brain surgeries, due to reports that the product was malfunctioning during brain surgeries. Despite the clear risk to patient safety, Mr. De Witte repeatedly pressured Plaintiff to put the product back on the market before the

attempted resolution of that malfunction was proven effective. She refused. As a result, she experienced constant verbal abuse and hostility from Mr. De Witte as she worked to confirm the Cerelink product was safe.

23. On October 22, 2022, Integra received a complaint through the internal employee hotline alleging that sterile and non-sterile products were being mixed at the company's Boston site and that site management had instructed employees to ignore the potential contamination. The hotline reporter brought the complaint to the FDA on November 3, 2022, after Integra refused to address the issue.

24. The FDA requires that the Chief Compliance Officer disclose all information that is patient, product, or quality related to the Chief Quality Officer so that a patient impact analysis can be completed. Integra had approximately 90 complaints while Plaintiff was CQO, but only four complaints had been partially shared with her during her tenure.

25. Integra's Policy for Managing Internal Reports, WWCP-040, applies to all internal reports submitted to the internal employee hotline that alleges issues or practices affecting product quality, design, processes/manufacturing, or post-market issues. It provides that "the Chief Quality Officer will be notified of quality-related internal reports within 24 hours of the Chief Compliance Officer becoming aware that the internal compliance report alleges a quality-related issue for prompt follow-up and investigation." However, only one of those complaints was disclosed to Plaintiff within 24 hours, and that complaint was only partially shared with Plaintiff. Specifically, Plaintiff was not alerted about the October 22, 2022 internal complaint submitted to the internal employee hotline until October 28, 2022, and she was told that the complaint focused on an issue that Integra was already purportedly resolving.

26. On November 17, 2022, Integra's Chief Compliance Officer ("CCO"), Tracy Redondo, closed the internal complaint made on October 22, 2022 for insufficient information, without informing Plaintiff.

27. Plaintiff suffered high blood pressure again on November 27, 2022, and was hospitalized. This occurred during the time that Integra was hiding information from Plaintiff about the October 22, 2022 internal complaint that was submitted. While Plaintiff was in the hospital, the CEO told her he wanted her to fly to New York for an executive meeting and dinner with his staff on Friday of that week. Plaintiff was released on Wednesday of that week from the hospital, but she was not able to fly. The CEO expressed his displeasure with Plaintiff for not attending that meeting despite her health issues.

28. The CEO also told Integra's Chief Regulatory Officer ("CRO"), Jessica Smith, to attend the executive meeting and dinner in New York, despite that she was also sick and told the CEO that she might have COVID. He insisted that she attend the event anyway and she tested positive for COVID on the next day, exposing the entire team to COVID.

29. Even after the October 22, 2022 internal complaint was closed, the hotline reporter continued to attempt to convince Integra to take action by putting notes under the Boston plant manager's door on December 5, 2022; December 14, 2022; and January 11, 2023. Plaintiff only learned that the October 22, 2022 internal complaint had been closed when the first note was received. The final note outlined 37 different lot numbers that the reporter stated had quality issues.

30. On December 7, 2023, Plaintiff, Ms. Smith, and Integra's internal counsel engaged outside counsel to assist [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

31. As a result of the information provided by the reporter concerning the 37 suspected lots, Plaintiff put all “new” manufacturing on hold, as of December 14, 2022. Nevertheless, Integra kept processing work in progress manufacturing at the Boston site until January 11, 2023, because Integra claimed it could not stop in the middle of manufacturing without scrapping it entirely. On January 17, 2023, Plaintiff notified the FDA that Integra had received an October 22, 2022 internal complaint regarding a culture issue and possible quality issues, and an investigation was opened.

32. On January 17, 2023, Plaintiff met with and notified the FDA via a Teams Meeting to disclose what action had been taken to ensure patient safety. Plaintiff also signed off on [REDACTED] [REDACTED] that Mr. Schwartz and Ms. Redondo had drafted, summarizing the issues. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

33. The FDA conducted a “for cause” on-site inspection of the Boston location from March 1, 2023, through May 16, 2023, to investigate the internal October 22, 2022 complaint, which was then referred to as a whistleblower complaint. During that investigation, the Lead FDA Auditor requested a copy of the transcript from the hotline complaint, which must be provided by law. Mr. Schwartz and Ms. Redondo refused to provide it. On March 7, 2023, the FDA informed Plaintiff that if the transcript was not produced by the following morning, then Integra would be written up for “Failure to Comply.” Plaintiff escalated the matter to Mr. De Witte. Only then did

Mr. De Witte order Ms. Redondo to give Plaintiff a copy of the transcript, and Ms. Redondo complied.

34. Even though Plaintiff's actions saved the company from flouting a demand from the FDA, Mr. Schwartz called Plaintiff later that evening and repeatedly yelled and swore at her, until Plaintiff threatened to hang up.

35. During the FDA inspection, it identified an issue with the manner in which Integra measured the level of endotoxin in the products. Plaintiff immediately put all product in global distribution centers and in inventory on hold using an internal form 801. This hold was executed on March 13, 2023.

36. [REDACTED]

37. Another issue arose on April 27, 2023, when outside lab results revealed that certain products manufactured at Integra's Boston site contained unacceptably high concentrations of

endotoxins, which can cause patient harms such as high fever, sepsis, meningitis, or death. The endotoxin levels detected by the outside lab results were 27 times higher than the levels detected by Integra's internal testing. A second test was performed, which verified that there was no lab error. Integra also had become aware of over 80 customer complaints in which patients reported high fevers, inflammation, revision surgical intervention, and infection. Two complaints also reported meningitis.

38. As a result of those findings, Integra's Product Safety Board agreed to destroy the existing inventory of those products. However, Mr. De Witte and Mr. Schwartz [REDACTED] [REDACTED] Plaintiff objected that it would be illegal to do so because the product they wanted to repurpose was built out of the same sheet of material as the recalled product that failed endotoxin testing. As a result, Mr. De Witte and Mr. Schwartz yelled at and verbally abused Plaintiff.

39. On one phone call, Plaintiff said, "Believe me, I want to save these just as much as you guys, but I don't want to break a regulation to do it," and Mr. De Witte responded, "Why not?" When Plaintiff continued to object to violating FDA regulations, Mr. De Witte dismissed the agency as a bureaucracy that "blocked common sense" and instructed Plaintiff to make sure "the bureaucracy doesn't squeeze out common sense."

40. Plaintiff endured a similar response on May 2, 2023, when she refused to allow Integra to ship inventory from the company's distribution center in Europe to Boston and illegally relabel it for sale in the United States. Even though labeling is considered part of the manufacturing process and the entire manufacturing process in Boston had been shut down, Mr. De Witte insisted that Plaintiff could load the printer equipment into the trunk of her car and drive them to Integra's manufacturing location in Mansfield, Massachusetts, to print the labels, and then

bring them back. Mr. De Witte claimed that “no one would know.” That plan would have been illegal because printer equipment and processes must be validated and documented before they are moved, and validation would have taken months. Additionally, the plan would have been illegal because it would have involved knowingly importing adulterated product into the United States, relabeling it, and then selling adulterated product through interstate commerce.

41. Integra Investor Day was held on May 4, 2023. Mr. De Witte and Mr. Schwartz intentionally uninvited Plaintiff and Ms. Smith from the meeting. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

42. On May 15, 2023, the FDA explicitly instructed Integra to recall all products manufactured at the Boston site for the previous five years. That recall occurred on May 16, 2023, and included all product manufactured at the Boston site between March 1, 2018, and March 22, 2023. It impacted 142 unique part numbers (parts ordered by hospitals) and 17,190 products in inventory across global distribution centers, of which 95% had already been sold to hospitals and potentially used in surgeries.

43. Only after the FDA’s instructions did Mr. De Witte and Mr. Schwartz stop demanding [REDACTED]

[REDACTED]

44. On June 1, 2023, Mr. Schwartz ridiculed, swore at, undermined, and humiliated Plaintiff in front of several people. At the meeting, Mr. Schwartz [REDACTED]

[REDACTED] This statement was disparaging and defamatory, particularly because it was made in front of Ms. Smith, an outside attorney from King & Spaulding and one of Plaintiff's employees. This statement was false because the issues at the Boston manufacturing facility pre-dated Plaintiff's employment and started in 2015.

45. Shortly after these incidents, Mr. De Witte refused to allow Plaintiff to take vacation, even though similarly-situated male executives were given significant paid time off and were allowed, in some cases, to take multi-week vacations out of the country.

46. Specifically, on June 16, 2023, Plaintiff asked to take vacation from July 5, 2023 to July 14, 2023, but Mr. De Witte denied her request. When Plaintiff texted him that she would plan on working, Mr. De Witte called her and said that he "could hear her crying through her text message." His comment was condescending and degrading, and he never would have made that comment to a male employee. Even when Plaintiff provided advance notice in November 2023 requesting vacation from February 5, 2024 to February 9, 2024, Mr. De Witte once again denied her request.

47. Male executives were permitted to take vacation in 2023, while Plaintiff was denied. Indeed, on July 28, 2023, Mr. De Witte sent an email to the executives, telling them to enjoy their vacations and that he would be on vacation from August 1, 2023 to August 14, 2023. Other male executives took multiple vacations lasting one to two weeks from 2022 to 2024, even though they were working on the same projects as Plaintiff. Notably, Mr. De Witte allowed Mr.

Schwartz to take multiple one to two-week vacations throughout 2022, 2023, and 2024, including vacations to Morocco, ski trips, and hiking in Italy. On information and belief, Mr. De Witte never denied any of the male executives' requests for vacation, and Plaintiff was the only executive who was required to obtain pre-approval.

48. On July 17, 2023, the FDA issued a Recidivist Warning Letter. Thereafter, Plaintiff had a one-on-one meeting with the Chairman of the Board of Directors to discuss the Boston situation, CEO performance, and new product innovation and design ideas.

49. On July 18, 2023, the Board met and posed numerous questions to Plaintiff about the Boston remediation. [REDACTED]

[REDACTED]

50. Also, on July 18, 2023, during a one-on-one meeting with a Board member,

[REDACTED]

51. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

52. In December 2023, Integra's Product Safety Board, which included Plaintiff, decided to recall Integra's cranial access kits manufactured at Integra's Salt Lake City facility, because there was evidence that the kits were not properly sterile. This issue was extremely serious because cranial access kits are used in brain surgery. Despite the strong statistical evidence in support of this decision, Mr. De Witte and Mr. Schwartz aggressively tried to override it. In one instance, Mr. Schwartz asked a statistician on Plaintiff's team [REDACTED]

[REDACTED]

[REDACTED]

53. Eventually, Mr. De Witte told Plaintiff that he would withhold her bonus if the cranial access kits recall proceeded. Mr. De Witte did not threaten to withhold a bonus from, or issue a similar ultimatum to, any male executive. Despite this threat, Plaintiff stood her ground. The cranial access kits were recalled on January 19, 2024, with 17,753 kits being recalled from 19 countries.

54. Mr. De Witte eventually gave Plaintiff her bonus in March after threatening to withhold it, but not until after she engaged legal counsel, and then only 70% of her bonus was paid to Plaintiff.

55. Plaintiff was not given performance reviews for 2022 and 2023 by Mr. De Witte, even though those performance reviews were required by Integra's internal processes in early February each year.

56. [REDACTED]

[REDACTED]

[REDACTED]

57. When Plaintiff attempted to push back on misleading changes, Mr. De Witte and Mr. Schwartz deliberately embarrassed her in meetings; used sarcastic, condescending, or otherwise unprofessional tones when speaking to her; disinvited her from meetings; and retaliated by threatening to withhold compensation from her.

58. Mr. De Witte subjected Plaintiff to disparate negative treatment as compared to her male colleagues, including micromanaging her, denying her benefits that her male counterparts enjoyed, and subjecting her to more rigorous scrutiny. Upon information and belief, none of the male executives were required to receive pre-approval from Mr. De Witte for their Board presentations, let alone six or more rounds of revisions for those presentations.

59. Integra's Board was repeatedly made aware of Mr. De Witte and Mr. Schwartz's misconduct but made no efforts to address the hostile and retaliatory environment that Mr. De Witte and Mr. Schwartz created.

60. Additionally, Plaintiff met with the new CHRO, Chantal Veillon, multiple times to bring to her attention the discrimination and hostile work environment by both Mr. De Witte and Mr. Schwartz. In one of the meetings, Ms. Veillon acknowledged that several other executives had raised the same type of concerns. Ms. Veillon acknowledged that there was a known problem and that she was working on resolving it behind the scenes.

61. As part of the remediation of the Boston facility, the FDA required Integra to hire an independent consultant to audit the Boston facility's manufacturing processes. This audit had to be submitted to the FDA by March 31, 2024. Integra hired Greenleaf Health to perform this audit. To prepare for the Greenleaf audit, Integra hired a different third-party auditor, QualityHub, to audit the Boston manufacturing processes multiple times. QualityHub's final audit was performed from January 22, 2024 to January 26, 2024. Based on the results, QualityHub believed that Integra was ready for the Greenleaf audit, though Integra still needed to complete final documentation.

62. [REDACTED]

63. In February 2024, Mr. De Witte became upset with an employee on Plaintiff's team because he had poor performance during an audit. Mr. De Witte stated that there "was no fucking way he's going to defend something he doesn't believe in" and that the employee "should get a bullet in the head."

64. On January 24, 2024, Integra received a new employee hotline complaint regarding quality issues, including falsification of records, at its site in Plainsboro, New Jersey. Integra

investigated the January 24, 2024 hotline complaint, but Plaintiff received few details about the information in the complaint. An employee on Plaintiff's quality team was part of the investigation team, but that employee was told that she could not share any information about the investigation with Plaintiff.

65. On February 20, 2024, Plaintiff met with a member of the Board of Directors [REDACTED]

[REDACTED]

[REDACTED] Integra recalled 22 products out of the Mansfield, Massachusetts manufacturing facility in Q3, after Plaintiff was constructively discharged from her employment at Integra. Upon information and belief, this was due to the FDA inspection that took place in March through April 2024. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

66. On February 23, 2024, Plaintiff's then-attorney sent a demand letter to Integra, advising Integra of Plaintiff's potential legal claims against it. Those claims included discrimination and retaliation because of Plaintiff's raising concerns about quality issues, instructing Integra to comply with FDA regulations, and attempting to raise material information to Integra's shareholders and Board of Directors. The demand letter also addressed a potential claim for sex discrimination because Integra subjected Plaintiff to significantly worse treatment than her male colleagues with respect to granting vacations and revising presentations to the Board of Directors.

67. On or about February 29, 2024, a meeting took place with all of Integra's chief officers, in which Mr. Schwartz verbally attacked both Mr. De Witte and Ms. Veillon, despite their efforts to try to stop him from escalating further.

68. On March 7, 2024, the anonymous whistleblower who had filed the employee hotline complaint on January 24, 2024 made a report to the FDA because the reporter was concerned Integra was not taking action to protect patient safety. The following day, Plaintiff demanded that Integra share all information with her relating to that report. She then received over 100 pages of documents from Integra leadership that previously had not been shared with her, including pictures of employees at the Plainsboro site falsifying records and of one employee destroying evidence. Integra had terminated four employees after confirming that they had

falsified quality records, cleaning records, and test results which revealed over 40 quality issues which directly impacted patient safety.

69. On March 7, 2024, there were multiple meetings with outside counsel to discuss [REDACTED]. Plaintiff determined that the whistleblower complaint was factually accurate and that there was no basis for informing the FDA that the allegations in the January 24, 2024 hotline complaint were false. Mr. Schwartz became upset and angry with that conclusion, [REDACTED], and started yelling at Plaintiff until Mr. De Witte stopped him and ended the call. A follow-up call took place with Plaintiff, Ms. Smith, and outside counsel. Plaintiff determined that there was potential patient safety risk and that the accusations were true based on video footage and other objective evidence, [REDACTED].

70. On March 8, 2024, Mr. De Witte demanded that Plaintiff sign and send a letter to the FDA, to be sent on March 12, 2024, stating that the whistleblower's allegations were false. Plaintiff refused to do so because that statement would have been false and required her to commit fraud. Based on the documents she had reviewed, Plaintiff knew that the Plainsboro site had numerous product quality and patient safety issues, including employees whom Integra had terminated after confirming that they had falsified records. In light of those numerous issues and conclusive evidence of misconduct, it would have been inaccurate and deceptive to tell the FDA that the whistleblower's allegations in the January 24, 2024 hotline complaint were false. Plaintiff communicated this directly to Mr. De Witte and Mr. Schwartz multiple times, who pressured Plaintiff to provide the FDA with false and deceptive information.

71. On March 10, 2024, Plaintiff met with a member of the Board of Directors of Integra. [REDACTED]

72. On March 11, 2024, Plaintiff had her then-attorney submit her resignation to Integra from her position as CQO for Integra due to the intolerable working conditions created for Plaintiff by Integra, including the hostile working environment, misrepresentations by Integra to Plaintiff, and the demand that she provide false information to the FDA.

73. Following her resignation, on May 6, 2024, during the earnings call when investors questioned the CEO regarding the need to re-visit long range planning for the Boston facility given the delayed restart of production, the CEO misleadingly told investors that “[Integra has] made changes to the operations and quality leadership and structure to ensure the right focus and capabilities is [sic] applied to Boston . . .” *Integra LifeSciences Q1 2024 Earnings Call* (May 6, 2024). Mr. De Witte made the statement about changing the quality leadership, for which Plaintiff was the Chief Quality Officer, implying that to fix the issues being addressed, Integra had to terminate Plaintiff as its Quality executive. Mr. De Witte’s statement was subsequently released to multiple media outlets and published, including but not limited to being published by Yahoo! Finance which had approximately 93 million subscribers and medical technology publications with over 134,000 unique visitors each month and over 56,000 newsletters per month. Mr. De Witte’s statement was a direct attack on Plaintiff’s character and livelihood as she was the head of Quality

at Integra. Mr. De Witte's statement was a false statement of fact, which was also clearly meant to blacklist Plaintiff and be retaliatory.

74. As a direct result of Plaintiff's constructive discharge from Integra and Mr. De Witte's false statement about Plaintiff, she has been unable to procure employment consistent with her employment and compensation with Integra. Prior to Mr. De Witte's statement on May 5, 2024, Plaintiff had been communicating with four large medical device companies regarding new employment. After Mr. De Witte's statement on May 5, 2024, none of those companies would communicate further with Plaintiff regarding employment. Plaintiff has applied for 121 jobs following her constructive discharge from Integra, but has been unable to obtain suitable employment.

75. Plaintiff has experienced, and is still experiencing, emotional distress as a result of the discriminatory, retaliatory, defamatory, and other unlawful actions by Integra. Plaintiff's emotional distress has caused depression, post-traumatic stress disorder, anxiety, nightmares, insomnia, and other mental health issues.

76. Plaintiff's emotional distress has manifested physical injury including hypertension, headaches, nausea and vomiting, gastrointestinal issues, and other health issues.

77. Plaintiff has been diagnosed with post-traumatic stress disorder and depression, and received mental health therapy from her psychologist.

PLAINTIFF'S DAMAGES

78. As a result of Integra's discriminatory, retaliatory, defamatory, and other unlawful actions, Plaintiff has suffered and will suffer damages including past and future wage loss, including lost compensation for base salary, cash incentives, equity incentives, stock options, lost

restricted stock awards for the third year of Plaintiff's employment with Integra, retention bonuses, insurance benefits, 401(k) match benefits, and other benefits.

79. Plaintiff has also suffered damages for mental anguish, emotional distress, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, and other pain and suffering.

80. Additionally, Plaintiff has and will incur attorney fees, costs, and expenses as a result of the actions of Integra during and following Plaintiff's employment with Integra.

COUNT ONE
VIOLATION OF THE MINNESOTA WHISTLEBLOWER ACT
MINN. STAT. § 181.932

81. Plaintiff realleges and incorporates by reference herein the foregoing allegations as though fully set forth herein.

82. Plaintiff was an employee and Integra was an employer for the purposes of the definition set forth in Minnesota Statutes § 181.931.

83. Minnesota Statutes § 181.932 prohibits an employer from discharging, disciplining, otherwise discriminating against, or penalizing an employee regarding the compensation, terms, conditions, or privileges of employment because "the employee...in good faith, reports a violation, suspected violation, or planned violation of any federal or state law or common law or rule adopted pursuant to law to an employer...."

84. Minnesota Statutes § 181.932 further prohibits an employer from discharging, disciplining, otherwise discriminating against, or penalizing an employee regarding the compensation, terms, conditions, or privileges of employment because the employee "refuses an employer's order to perform an action that the employee has an objective basis in fact to believe

violates any state or federal law or rule or regulation adopted pursuant to law, and the employee informs the employer that the order is being refused for that reason.”

85. On repeated occasions, Plaintiff reported violations, suspected violations, and planned violations of FDA regulations, OSHA, and internal Integra policies, including without limitation to, among others, CEO Mr. De Witte, CLO Mr. Schwartz, CRO Ms. Smith, CCO Ms. Redondo, and various members of the Integra Board of Directors.

86. Because of Plaintiff’s reports to Integra and outside agencies including the FDA, Integra disciplined, discriminated against, and penalized Plaintiff regarding her compensation, withholding performance reviews and corresponding additional compensation which would have been provided to Plaintiff based upon those performance reviews, benefits, time off, terms, conditions, and privileges of employment.

87. Plaintiff was constructively discharged after she was ordered to sign an inaccurate and deceptive letter to the FDA.

88. As a result of Integra’s violation of Minnesota Statute § 181.932, Plaintiff has suffered damages, including but not limited to past and future wage loss, emotional distress, mental anguish, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, pain and suffering, and other damages, in an amount in excess of \$50,000.00, to be determined at trial, by default judgment, or by dispositive motion; and for and any injunctive and other equitable relief as determined by the Court.

COUNT TWO
DISCRIMINATION ON BASIS OF SEX
MINNESOTA HUMAN RIGHTS ACT
MINN. STAT. §§ 363A.01, *et. seq.*

89. Plaintiff realleges and incorporates by reference herein the foregoing allegations as though fully set forth herein.

90. Plaintiff was an employee and Integra was an employer, for the purposes of the definitions set forth in Minnesota Statutes § 363A.03.

91. Minnesota Statutes § 363A.08 prohibits an employer, because of sex, from discriminating against a person “with respect to hiring, tenure, compensation, terms, upgrading, conditions, facilities, or privileges of employment.”

92. Minnesota Statutes § 363A.08 further provides that it is unlawful for an employer, because of sex, to discharge an employee.

93. Integra discriminated against Plaintiff in the following manner:

a) Ridiculing, yelling at, and degrading Plaintiff in front of her colleagues for doing her job, while similarly-situated male colleagues were not treated in such a manner.

b) Refusing to allow her to take vacation, regardless of the notice she provided, while similarly-situated male colleagues were allowed to take lengthy and long-distance vacations.

c)

[REDACTED]

d) Threatening not to pay her a bonus if the recall proceeded, while similarly-situated male colleagues did not receive threats that they would not receive a bonus.

e) Intentionally creating working conditions that a reasonable person in Plaintiff's situation would find intolerable, while similarly-situated male colleagues were not subjected to intolerable working conditions.

94. Integra discriminated against Plaintiff on the basis of her sex.

95. Integra constructively discharged Plaintiff on the basis of her sex.

96. Integra's discrimination against Plaintiff related to her compensation, facilities, privileges of employment, and Plaintiff's terms and conditions of employment, and prevented her from discharging her duties as Chief Quality Officer.

97. The discrimination described herein was deliberate and intentional and committed with malice, reckless disregard, or deliberate disregard for Plaintiff's rights.

98. Integra presents no legitimate reason for this discrimination and its stated motivation is pretext for discrimination.

99. As a direct and proximate result of Integra's sex discrimination, Plaintiff has suffered damages, including but not limited to past and future wage loss, emotional distress, mental anguish, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, other pain and suffering, and punitive damages, in an amount in excess of \$50,000.00, to be determined at trial, by default judgment, or by dispositive motion; and for and any injunctive and other equitable relief as determined by the Court.

COUNT THREE
REPRISAL
MINNESOTA HUMAN RIGHTS ACT
MINN. STAT. §§ 363A.01, *et. seq.*

100. Plaintiff realleges and incorporates by reference herein the foregoing allegations as though fully set forth herein.

101. Plaintiff was an employee and Integra was an employer for the purposes of the definition set forth in Minnesota Statute § 363A.03.

102. As set forth in Count Two, Integra discriminated against Plaintiff on the basis of her sex in violation of the Minnesota Human Rights Act.

103. Plaintiff opposed practices forbidden under the Minnesota Human Rights Act, including discrimination against her on the basis of her sex. Furthermore, Plaintiff, on numerous occasions, brought quality concerns to Integra's attention in an attempt to obtain remedial action.

104. Minnesota Statute § 363A.15 prohibits an employer from "intentionally engag[ing] in any reprisal against any person because that person...opposed a practice forbidden under this chapter...."

105. The Minnesota Human Rights Act specifically defines reprisal to include retaliation, and further prohibits Integra from retaliating by departing from any customary employment practice.

106. Because Plaintiff opposed Integra's discriminatory conduct, she was subjected to reprisal, including denial of benefits and privileges that were otherwise available to similarly-situated male colleagues, further discrimination, outright harassment, retaliation, hostility, and refusal to treat Plaintiff with respect and professionalism, in the workplace, and exclusion from benefits that others were entitled to receive.

107. The discrimination described herein was deliberate and intentional and committed with malice, reckless disregard, or deliberate disregard for Plaintiff's rights.

108. As a direct and proximate result of Integra's reprisal, Plaintiff has suffered damages, including but not limited to past and future wage loss, emotional distress, mental anguish, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, other pain and suffering, and punitive damages, in an amount in excess of \$50,000.00, to be determined at trial, by default judgment, or by dispositive motion; and for and any injunctive and other equitable relief as determined by the Court.

COUNT FOUR
CREATION OF HOSTILE WORK ENVIRONMENT
MINNESOTA HUMAN RIGHTS ACT
MINN. STAT. §§ 363A.01, et seq.

109. Plaintiff realleges and incorporates by reference herein the foregoing allegations as though fully set forth herein.

110. Plaintiff was an employee and Integra was an employer for the purposes of the definition set forth in Minnesota Statutes § 363A.03.

111. As set forth in Counts Two and Three above, Defendant discriminated against Plaintiff, and subjected Plaintiff to unwelcome harassment, on the basis of protected characteristics under the MHRA, including Plaintiff's sex.

112. Plaintiff was exposed to disadvantageous terms and conditions of her employment to which male colleagues were not exposed, such as deprivation of vacation, compensation, and bonuses.

113. That harassment affected the terms, conditions, or privileges of employment, as Plaintiff was not able to properly perform her duties as Chief Quality Officer.

114. Additionally, the harassment was sufficiently severe or pervasive as to affect the terms, conditions, or privileges of her employment, and was so intimidating, offensive, and hostile to poison the work environment at Integra.

115. Integra was aware of the harassment, including the other officers and the Integra Board of Directors, based upon numerous reports made by Plaintiff. Despite this knowledge, Integra failed to take remedial action.

116. As a result of Integra's conduct, a reasonable person in Plaintiff's situation would find that the working conditions were intolerable. Moreover, Integra's discriminatory conduct was

severe and caused substantial harm to Plaintiff, was humiliating to Plaintiff, and unreasonably interfered with Plaintiff's work performance.

117. As a direct and proximate result of Integra's creation of a hostile work environment, Plaintiff has suffered damages, including but not limited to past and future wage loss, emotional distress, mental anguish, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, other pain and suffering, and punitive damages, in an amount in excess of \$50,000.00, to be determined at trial, by default judgment, or by dispositive motion; and for and any injunctive and other equitable relief as determined by the Court.

COUNT FIVE
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

118. Plaintiff realleges and incorporates by reference herein the foregoing allegations as though fully set forth herein.

119. Integra engaged in extreme and outrageous conduct by its treatment of Plaintiff as described herein, including by its harassment, verbal abuse, retaliation after she reported violations of law, and instructions that she violate the law.

120. Integra's conduct as described herein, including its harassment, verbal abuse, retaliation after she reported violations of law, instructions that she violate the law, and discrimination based on sex, was intentional.

121. Plaintiff has suffered severe emotional distress because of the intentional, extreme, and outrageous conduct of Integra.

122. As a direct and proximate result of Integra's intentional, extreme, and outrageous conduct, Plaintiff has suffered damages, including but not limited to past and future wage loss, emotional distress, mental anguish, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, and other pain and suffering, in an amount in excess of \$50,000.00, to be

determined at trial, by default judgment, or by dispositive motion; and for and any injunctive and other equitable relief as determined by the Court.

COUNT SIX
DEFAMATION

123. Plaintiff realleges and incorporates by reference herein the foregoing allegations as though fully set forth herein.

124. In Integra's Earnings Call on May 6, 2024, Integra stated that it "made changes to the operations and quality leadership and structure to ensure the right focus and capabilities is applied" to issues at the Boston plant, directly implying that Plaintiff did not have the right focus or capabilities to lead the quality team.

125. Additionally, Integra ridiculed Plaintiff and made false statements about her livelihood in front of her employees, peers, and external experts that undermined her credibility and directly damaged her reputation.

126. Integra made salacious and untrue statements about Plaintiff's reputation to the public.

127. Integra's defamatory statements were representations of facts which were false.

128. Integra's statements were untrue and made with knowledge of their falsity.

129. Integra's false statements have adversely affected Plaintiff's reputation.

130. Integra's false statements about Plaintiff adversely affected Plaintiff in her business, trade or profession.

131. As a result of Integra's defamation, Plaintiff has been unable to obtain employment commensurate with her employment position with Integra.

132. As a result of the wrongful acts alleged herein, Plaintiff has suffered actual and per se damages, including but not limited to past and future wage loss, loss of potential income,

emotional distress, mental anguish, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, and other pain and suffering, in an amount in excess of \$50,000.00, to be determined at trial, by default judgment, or by dispositive motion; and for and any injunctive and other equitable relief as determined by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court award Plaintiff the following relief:

1. Entering judgment in favor of Plaintiff and against Integra for back pay, front pay, compensatory damages, reasonable attorney's fees, costs, disbursements, and other monetary damages, in an amount in excess of \$50,000.00 for Count One of Plaintiff's Complaint.

2. Entering judgment in favor of Plaintiff and against Integra for back pay, front pay, mental anguish, emotional distress, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, other pain and suffering, punitive damages under the Minnesota Human Rights Act, and the Minnesota Human Rights Act multiplier, in an amount in excess of \$50,000.00 for Count Two of Plaintiff's Complaint.

3. Entering judgment in favor of Plaintiff and against Integra for back pay, front pay, mental anguish, emotional distress, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, other pain and suffering, punitive damages under the Minnesota Human Rights Act, and the Minnesota Human Rights Act multiplier, in an amount in excess of \$50,000.00 for Count Three of Plaintiff's Complaint.

4. Entering judgment in favor of Plaintiff and against Integra for back pay, front pay, mental anguish, emotional distress, humiliation, embarrassment, loss of reputation, medical injury,

medical monitoring, other pain and suffering, punitive damages under the Minnesota Human Rights Act, and the Minnesota Human Rights Act multiplier, in an amount in excess of \$50,000.00 for Count Four of Plaintiff's Complaint.

5. Entering judgment in favor of Plaintiff and against Integra for mental anguish, emotional distress, humiliation, embarrassment, loss of reputation, medical injury, medical monitoring, and other pain and suffering, in an amount in excess of \$50,000.00 for Count Five of Plaintiff's Complaint.

6. Entering judgment in favor of Plaintiff and against Integra for actual damages, loss of reputation, lost income, and per se damages, in an amount in excess of \$50,000.00, for Count Six of Plaintiff's Complaint.

7. Awarding Plaintiff prejudgment interest.

8. Awarding Plaintiff her reasonable attorney's fees, costs, and disbursements otherwise recoverable by law or rule.

9. Granting Plaintiff such other and further relief as the Court deems just and equitable under the circumstances.

JURY TRIAL DEMAND

Plaintiff demands a jury trial as to all claims so triable.

Dated: November 8, 2024

By: /s/ Jonathan D. Miller

Jonathan D. Miller (#292485)
Debra L. Weiss (#288810)
Anthony W. Joyce (#0400823)
Meagher + Geer, P.L.L.P.
33 South Sixth Street, Suite 4300
Minneapolis, MN 55402
(612) 338-0661
jmiller@meagher.com
dweiss@meagher.com
ajoyce@meagher.com

Attorneys for Plaintiff Susan Krause

ACKNOWLEDGMENT

The undersigned hereby acknowledges that costs, disbursements and reasonable attorney and witness fees may be awarded pursuant to Minn. Stat. §549.211 to the party against whom the allegations in this pleading are asserted.

Dated: November 8, 2024

/s/ Jonathan D. Miller

Jonathan D. Miller (#292485)
Debra L. Weiss (#288810)
Anthony W. Joyce (#0400823)