[redacted]

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEVADA

GLORIA JEAN ROGET, Individually and As Special Administrator and Heir to the Estate of **ANDRE CARL ROGET**, Deceased, Plaintiff, vs. **MEDTRONIC, INC.**, a California Corporation, **MEDTRONIC MINIMED, INC.**, a Minnesota Corporation, and **DOES 1-20, ROE CORPORATIONS 1-20,** Defendants.	Case No.:

PLAINTIFF'S ORIGINAL COMPLAINT FOR WRONGFUL DEATH, SURVIVAL ACTIONS AND JURY DEMAND

COMES NOW Plaintiff, GLORIA JEAN ROGET, Individually (hereinafter "Plaintiff") and as Special Administrator and Heir to the Estate of ANDRE CARL ROGET, Deceased

(hereinafter "Decedent"), by and through the undersigned counsel, who brings this action for wrongful death pursuant to Section NRS 41.085 of the Nevada Rules of Civil Procedure, and come now Plaintiff who brings this survival action pursuant to NRS 41.130 of the Nevada Rules of Civil Procedure against Defendants, MEDTRONIC, INC., and MEDTRONIC MINIMED, INC., DOES 1-20 and ROES 1-20 (collectively "Defendants"). As grounds thereof, Plaintiff states the following:

INTRODUCTION

1. This is a products liability action against Defendants for the failure of their medical device, prescribed to Decedent. The device was used by Decedent, and because of defects related to the device, Decedent suffered an insulin-induced coma that led to his eventual death on May 14, 2020.

2. This complaint alleges claims under parallel state law duties based on the Defendants' failure to conform with the FDA's Pre-Market Approval (PMA) process for this medical device and failure to conform and violations of FDA regulations.

3. The Decedent was a Type II diabetic and was prescribed the Defendants' insulin infusion medical device – Medtronic's MiniMed 630G insulin infusion pump - intended and used for the treatment of Type II diabetes mellitus. The Decedent then used the device that malfunctioned and put him in an insulin-induced coma causing his eventual death. Plaintiff and Decedent were informed and believed and thereon allege that these devices, were researched, designed, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, placed in the stream of commerce, and sold or otherwise provided to Decedent by Defendants, MEDTRONIC MINIMED, INC. and/or MEDTRONIC, INC. and/or DOES 1-20 and/or ROES 1-20.

JURISDICTION AND VENUE

4. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiff and Defendants. Defendants are either incorporated and/or have their principal place of businesses outside of the State of Nevada in which the Plaintiff resides.

5. The amount in controversy between Plaintiff and Defendants exceeds $75,000, exclusive of interest and cost.

6. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

7. Venue is proper within this district pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and is subject to personal jurisdiction in this district. Furthermore, Defendants sell, market, and/or distribute insulin pumps within the District of Nevada. Also, a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

PARTIES

8. Plaintiff is an adult citizen and resident of Las Vegas, Clark County, Nevada.

9. Plaintiff is the surviving spouse and personal representative of Decedent's estate.

10. Plaintiff and Decedent were married on May 13, 1967, and remained married until Decedent's death.

11. The Decedent died on May 14, 2020, in Las Vegas, Clark County, Nevada.

12. At all times material hereto, Defendant, MEDTRONIC, INC., was and is a Foreign For-Profit Corporation (incorporated in Minnesota) which, at all times relevant to this lawsuit, was authorized to do business in the State of Nevada, and which operated, conducted, engaged in, and/or carried on a business or business venture throughout the State of Nevada for

which it received substantial revenue. Its principal place of business is located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. This defendant may be served via its Registered Agent: **Corporation Service Company, 112 North Curry Street, Carson City, Nevada 89703**.

13. At all times material hereto, Defendant, MEDTRONIC MINIMED, INC., was and is a Foreign For-Profit Corporation (incorporated in Delaware) which was doing business throughout the State of Nevada for which it received substantial revenue. Its principal place of business is located at 18000 Devonshire Street, Northridge, California 91325. This Defendant may be served via its Registered Agent: **Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808**.

14. Plaintiff does not know the true names and identities of those Defendants designated as DOES I through 20, ROES I through 20 inclusive, but alleges that each of said fictitiously named Defendants was negligently and unlawfully responsible for the events herein described, and for the injuries and damages sustained by Plaintiff and Decedent. Plaintiff will ask leave of court to amend this complaint when the identity of each such fictitiously named Defendant has been ascertained.

15. Decedent's injuries, including death, proximately resulted from the wrongful, reckless, and negligent acts and omissions, and fraudulent misrepresentations of Defendants and/or each of them, all of which occurred within the venue of this court.

16. At all times relevant to this action, the term "Defendants" includes all Defendants unless otherwise noted, including but not limited to MEDTRONIC MINIMED, INC., MEDTRONIC, INC., DOES 1 through 20, and ROES 1 through 20, inclusive.

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17. At all times material hereto, Defendants were the manufacturer(s) and/or sellers and/or distributors of the MiniMed Insulin Infusion Pumps, Model Nos. 630G and 670G are described as an "artificial pancreas," designed, manufactured, and intended to monitor a patient's blood glucose levels in real-time and deliver and/or suspend basal and bolus insulin doses under pre-set but modifiable parameters.

THE COMPANIES

18. Medtronic is a global healthcare products company, with annual revenue in the billions of dollars. Medtronic touts its leadership in the medical device industry, explicitly representing that it has 25 years of continuous leadership in diabetes device solutions that improve patients' lives. Medtronic claims to be passionate about diabetes care, with a highly trusted brand and a proven track record for advancing solutions. This claim is echoed in part of Medtronic's mission statement. Medtronic vows to "strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity and service."

19. Despite Medtronic's stated mission, infusion sets have been the subject of a myriad of problems and defects over the years. For example, in sharp contrast to Medtronic's Website, are statements from a June 1, 2009, letter from the United States Food and Drug Administration ("FDA") to William A. Hawkins, Medtronic's president and chief executive officer, regarding Medtronic PR Operations Co. In criticizing Medtronic's manufacturing and report process, the FDA cited Medtronic for:

> Failure to report to the FDA no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device you have on the market: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that you market would be likely to cause

> or contribute to the death or serious injury, if the malfunction were to recur...

20. In contravention of applicable federal regulations, Medtronic has failed to report an incident involving a MiniMed insulin pump in which "device failure or malfunction may have contributed to or caused the user's hospitalization and the device's malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

21. The FDA also found fault with the personnel that Medtronic entrusted at its manufacturing facility in Puerto Rico when determining whether a Medtronic device was dangerous. Specifically, the FDA cited Medtronic for:

> Failure to have a person who is qualified to make a medical judgment reasonably conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury, if it were to recur, as required by [United States Federal Law.] Personnel qualified to make a medical judgment include physicians, nurses, risk managers and biomedical engineers under [United States Federal Law.]

22. According to FDA Investigators, this plant had a wide range of problems that included lax testing of products for defects, improper record-keeping, and employing someone with insufficient training as a medical expert to determine danger or defects. Said employee only had a high school diploma with some additional in-house training. In listing these and other violations, the FDA concluded that the problems may be symptomatic of serious problems in Medtronic's manufacturing process and its quality controls.

23. None of the cited violations reflect Medtronic's promise to strive "without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of dedication, honesty, integrity, and service."

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24. On or about June 29, 2009, these issues led to a Class 1 recall of many of the Defendants' insulin infusion sets labeled Paradigm Quick-Set Infusion Sets. Said recall included lots manufactured between 2007 and 2009. Approximately three million disposable infusion sets were recalled.

25. On or about June 7, 2013, Medtronic MiniMed Paradigm infusions sets were recalled via a Class 1 recall. The recall was issued "because of a potential safety issue that can occur if insulin or other fluids come in contact with the inside of the tubing connector. If this occurs, it can temporarily block the vents that allow the pump to properly prime."

26. The 2013 recall admitted that "[t]his can result in too much or too little being delivered resulting in hypoglycemia or hyperglycemia which can be severe and lead to serious illness."

27. The 2013 recall was virtually identical to the 2017 recall with regard to the infusion set at issue in this case. The same problems fluid causing a vent blockage resulting in the same outcomes over-delivery of insulin are at issue in both recalls.

28. It is clear that Medtronic did not resolve the problem with their product which resulted in the 2013 recall. Medtronic marketed the subject infusion sets without fixing the problem, resulting in another recall for the same defect in 2017.

29. Unfortunately, non-conformance with FDA's approval and regulations, including past recalls and problems associated with Medtronic infusion sets did not result in Medtronic putting safer products into the stream of commerce for use by Andre Carl Roget.

THE CURRENT RECALL

30. On September 7, 2017, Medtronic issued an "Urgent Medical Device Recall" regarding Medtronic MiniMed Infusion Sets.

31. The Recall Notice states that "Medtronic has become aware of recent report of potential over-delivery of insulin shortly after an infusion set change." Medtronic further notes that it has received reports of hypoglycemia requiring medical attention related to this issue, which Medtronic concedes can result in "hypoglycemia and in extreme cases, death."

32. The Recall Notice states that this problem is caused by fluid blocking the infusion set membrane during the priming/fill tubing process, which prevents the infusion set from working properly. The result can be fast delivery of multiple days' worth of insulin.

33. The Recall Notice also announces that Medtronic has an alternate infusion set design, which contains a "new and enhanced membrane material that significantly reduces the risk."

34. As a result of the defective MiniMed Infusion Sets, Decedent received a large quantity of insulin, which resulted in severe hypoglycemia, diabetic coma, and his death on May 14, 2020.

35. On November 21, 2019, Medtronic issued an "Urgent Field Safety Notification" to patients warning them of the potential risk of hyperglycemia (high blood glucose) or hypoglycemia (low blood glucose) associated with broken or missing pump retainer rings on the 630G and 670G model insulin infusion pumps. Exhibit 1. The retainer ring enables the insulin-containing reservoir to be locked into place. Medtronic alerted patients to "reported incidents of a loose reservoir that can no longer be locked into the pump . . . due to a broken or missing retainer ring that prevents a proper lock." *Id.* The Field Safety Notification continued:

> If the reservoir is not properly locked into the pump, it could lead to over or under delivery which could then result in hypoglycemia or hyperglycemia.
>
> - For example, if the pump retainer ring is broken or becomes detached from the pump, and the user inserts the reservoir back into the pump while the

> infusion set is still connected to the body, it could result in a rapid infusion of insulin, which could cause hypoglycemia. The under delivery of insulin could occur if the reservoir is not properly locked into place by the retainer ring, creating a space between the pump and the reservoir, and preventing the pump from pushing the expected insulin into the body, which could cause hyperglycemia. *Id*.

Medtronic instructed patients to discontinue using the pump and consult with their healthcare providers "if the reservoir does not lock into the pump or the retainer ring is loose, damaged or missing." If, however, the reservoir "properly locks in place by the reservoir ring" patients were instructed to "continue to use your pump."

Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump

36. Almost exactly 3 months later, on February 12, 2020, Medtronic issued a recall of more than 300,000 of their 630G and 670G insulin pumps in the U.S. Upon information and belief, this is the entire installed base of these models pumps in the U.S. It is also believed that more than 100,000 additional units outside of the U.S. were subject to the recall. The FDA

classified the recall as a Class I recall because it deemed the use of these devices under the circumstances "may cause serious injuries or death." Exhibit 2. The affected lots are those manufactured before October 2019 and distributed between September 2016 and October 2019 (630G model) or manufactured before August 2019 and distributed between June 2017 and August 2019 (670G model). *Id.* The FDA reported that Medtronic had received a total of more than 26,400 complaints of which 2,175 reported injuries with one (l) known death. *Id*. This letter was sent on March 5, 2020. Exhibit 3.

37. Consistent with the Quality Systems Regulations, 21 C.F.R. *§* 820, which govern the manufacture of Class III pre-market approval ("PMA") medical devices, the November 2019 "Urgent Field Safety Notification" which preceded the February 2020 Class I recall would have been the result of Medtronic initiating a "Corrective and Preventative Action" ("CAPA") process in response to complaints received from patients. That CAPA process would have been triggered when Medtronic detected a "safety signal" through post-marketing complaints about the device. As its name suggests, the purpose of the CAPA is to identify the cause of the problem and develop "corrective" measures for the problem and take "preventative" actions to make sure that non-conforming products do not make it to market. *See* 21 C.F.R. § 820.100. A foundational aspect of a CAPA is a "root cause analysis" to determine, among other things, if the problem is one of design, manufacturing, or potentially both.

THE PUMPS

A. Model 630G

38. The 630G is the successor to the 530G, Medtronic's first "artificial pancreas" approved in 2013. The 530G differed from all of its predecessors in that the real-time sensor values from the continuous glucose monitoring functions of the pump could directly interact

with insulin delivery through the "threshold suspend feature" which could automatically suspend insulin delivery for up to two hours if sensor glucose values fell below a threshold and the patient failed to respond to alerts and alarms. Medtronic described the "major difference" between the 530G and 630G, which was approved for marketing on August 10, 2016, as an updated display screen that presented in color. The 630G used the same "threshold suspend" algorithm as the 530G.

B. Model 670G

39. The 670G was approved for marketing six weeks after the 630G on September 28, 2016, as an "Automated Insulin Delivery System," which included an "Auto Mode" feature which could "automatically adjust basal insulin delivery using continuous glucose monitor data [and] automatically increase or decrease the amount of insulin delivered based on sensor values." As described in the Summary of Safety and Efficacy Data (SSED), the 670G has an "Auto Mode," a "new tool" that

> uses an algorithm to automatically adjust basal insulin delivery using continuous glucose monitor data. When in Auto Mode, the pump responds to fluctuations in interstitial fluid glucose levels measured by the continuous glucose monitor; the Auto Mode feature can automatically increase or decrease the amount of basal insulin delivered based on sensor glucose values.
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> The Auto Mode algorithm is designed to adjust the user's basal insulin rates to try to keep them at a target blood glucose level. The standard target glucose setting in Auto Mode is 120 mg/dL, and the target can also be set temporarily to 150 mg/dL for exercise and other events. In addition, blood glucose readings above 150 mg/dL will prompt the Auto Mode feature to calculate if a correction bolus is needed; if needed, a correction bolus will be recommended to the users, who can choose whether they want to deliver that correction bolus. Users should check their blood glucose levels using a blood glucose meter before administering a correction bolus.

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STATEMENT OF DECEDENT'S FACTS

40. Decedent was diagnosed as Type II diabetic in 1999. As a result, he was prescribed to use an insulin infusion pump which he used and would receive a new pump approximately every five (5) years.

41. In January 2019, Decedent received his new Medtronic MiniMed 630G insulin pump from the Defendants. Since January 2019, Decedent used the Medtronic MiniMed 630G Insulin Pump, serial number NG2135451H, until his hypoglycemic episode that resulted in going into a diabetic coma for seven days and ultimately dying on May 14, 2020.

42. Because of his diabetic condition, Decedent managed his diabetes through the use of insulin pump therapy, specifically; by using the Medtronic MiniMed 630G Insulin Pump to deliver the necessary amount of insulin into his bloodstream to properly treat his diabetes. When functioning correctly, these devices and their components mimic how a healthy pancreas works by delivering continuous and controlled doses of rapid-acting insulin, 24 hours a day, to match the user's body's needs.

43. On April 18, 2020, Decedent was at his home and went to bed early due to not Decedent feeling well. The Medtronic MiniMed 630G MMT-1755K Insulin Pump at issue was part of an FDA Class 1 Device Recall on November 21, 2019. Unfortunately, Plaintiff states that she does not remember receiving any notification of the recall, nor does she remember her husband receiving any notification of the recall. Thus, Decedent continued using his insulin pump.

44. On the morning of April 19, 2020, Plaintiff found her husband, Decedent, unconscious and unresponsive in their bedroom. Plaintiff called 9-1-1, and the paramedics arrived to treat Decedent.

45. The Decedent was rushed by ambulance to SHM – Summerlin Hospital Medical Center in Las Vegas, Nevada, where it was determined that he was suffering from profound hypoglycemia due to his insulin pump.

46. The collective Defendants, along with their agents and employees, negligently caused the defective insulin pumps to be designed, manufactured, assembled, distributed, and sold to members of the public, and they further negligently failed to remove the recalled infusion sets from the marketplace and stream of commerce after they had knowledge of the defects as well as the recall.

47. The Defendants designed, manufactured, marketed, and distributed the Medtronic MiniMed 630G Insulin Pump and Pro Set Infusion Sets, which were marketed to deliver insulin to a person with diabetes in measured amounts. The MiniMed pump was manufactured with a retainer ring designed to lock the patient's insulin cartridge into place in the pump's reservoir compartment. Pro Set Infusion Sets consist of a membrane and disposable plastic tubes which transport insulin from the pump to the patient's body. The Medtronic MiniMed 630G Insulin Pump and Pro Set Infusion Sets are used in conjunction with one another to help people with diabetes regulate their blood sugar by providing a constant source of insulin. They provide an alternative to daily injections of insulin. The pump connects to flexible plastic tubing that delivers insulin to the body. Users set the pump to deliver insulin throughout the day. It can be programmed to release larger doses at meals or when blood sugar levels are too high.

48. Plaintiff, nor the Decedent, had any way of knowing that the Medtronic MiniMed 630G Insulin Pump and Pro Set Infusion Sets that he used on the night of the incident were defective in design, manufacture, and marketing, and that, even when used in conformance

with Defendants' instructions, were prone to deliver doses of insulin incorrectly and in life-threatening doses.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT PRODUCT LIABILITY
(Against all Defendants, Does 1-20 and Roes 1-20)

49. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

50. Plaintiff and Decedent hereby assert a strict liability claim for defective manufacturing pursuant to applicable Nevada law.

51. Each of the Defendants are medical device companies engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise involved in placing various medical devices into the stream of commerce, intended human use including facilitating the infusion and/or ingestion of drug products such as insulin for diabetes control.

52. At the times and places mentioned above and at all times material thereto, each of the Defendants, held themselves our as knowledgeable and possessing the requisite skill particular to the research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale of such products.

53. At the times and places aforesaid, and at all times material hereto, Defendants, and each of them, placed into the stream of commerce medical devices which were unreasonably dangerous through defective manufacture and/or which failed to conform to the specifications approved by the FDA and/or failed to function as intended and/or malfunctioned and were therefore not safe and effective, and were unfit for their intended purpose and

foreseeable uses and were in a defective and dangerous condition in violation of the approvals received by the FDA, and the requirements thereunder.

54. Defendants, and each of them, caused or otherwise allowed, enabled or facilitated the placement of unreasonably dangerous products in a defective condition, and in violation of the FDA's requirements, into the stream of commerce, and are strictly liable in tort.

55. As a foreseeable, direct, and proximate result of the direct and proximate cause of the manufacturing defects and the Defendants' conduct alleged herein, Decedent sustained injuries and damages, including his death for which a cause of action is hereby stated.

SECOND CAUSE OF ACTION
NEGLIGENCE
(Against all Defendants, Does 1-20 and Roes 1-20)

56. The Plaintiff and Decedent incorporate, adopts by reference, and reallege each and every allegation of this Complaint the same as though specifically set out herein again.

57. At all times relevant to this Complaint, Defendants had a duty to assure that those products that they placed into the stream of commerce were free of defects and reasonably fit and suitable for their intended or foreseeable uses and conformed to the FDA-approved specifications.

58. At all relevant times material hereto, Defendants, and each of them, placed or caused to be placed into the stream of commerce, a product or products which were in a defective and unreasonably dangerous condition, not in conformance with FDA-approved specification and/or not reasonably fit or suitable for their intended or foreseeable uses or otherwise not conforming with specifications.

59. Defendants and each of them knew or should have known in the exercise of reasonable care that their MiniMed products were defective and in a dangerous condition and/or

not reasonably fit or suitable for their intended or foreseeable purpose uses and negligently placed these non-conforming and defective products into the stream of commerce where they would be expected to be utilized by insulin-dependent diabetics like Decedent.

60. Injuries and damages sustained by the Decedent, including his death, were both proximately caused and a reasonably foreseeable result of Defendants' products and conduct.

61. As a foreseeable, direct, and proximate result of Defendants' negligence, Decedent and Plaintiff and each of them was injured, with Decedent suffering bodily injury, harm, and ultimately his death, and both Plaintiff and Decedent sustained damages compensable under Nevada law.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against all Defendants, Does 1-20 and Roes 1-20)

62. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

63. At all relevant times, Defendants expressly represented and warranted through written literature, including but not limited to product labeling, patient package inserts, articles in medical journals, advertising, and other documentation and/or promotional materials directed to Decedent's physician, and/or the Decedent and Plaintiff, by and through Defendants' authorized agents or sales representatives orally and in writing that the Medtronic MiniMed Infusion Sets and MiniMed 630G Insulin Pump were safe and free from defects, effective, and fit and proper for their intended use or foreseeable uses in accordance with and conformed to FDA regulations and specifications. Said representations were in the form of marketing materials, device information, and product materials provided to Andre Roget, Decedent. Decedent justifiably relied on said representations and express warranties in electing to use said

product.

64. For example, on its webpage, Medtronic touts that it is "delivering on our promises through medical innovation" and invited viewers to "discover our full breadth of reliable, safe, high-quality devices." Following the hyperlink "Browse Our Products" leads to a page in which additional links for the 630G and 670G are available. Clicking on the 630G link leads to a promotional brochure captioned "Better Control, Fewer Lows. Making it easier for patients to manage their diabetes – so they can live exceptional lives."

65. On Page 4 of the Medtronic brochure, Medtronic touts that "93% of patients who use SmartGuard technology [incorporated in the closed loop system] say they feel more secure and confident in treating their diabetes" The source of this data can be found two pages later embedded in a dense footnote in very small type and is drawn from "user evaluations" with the "data on file [at] Medtronic MiniMed." This is potentially misleading because it suggests that 93% of all users, rather than just the users who completed the evaluations feel more secure and confident.

66. Similarly, a promotional brochure for patients promises "Freedom" through "breakthrough diabetes technology that lets you focus more on living your life." The device is described as representing "revolutionary technology [that] automatically adjusts to your life. On page 6 of the brochure in a footnote in small print, the "revolutionary technology" is noted to refer to the "SmartGuard Auto Mode feature" which "can automatically increase or decrease insulin delivery based on continuous glucose monitoring (CGM) values."

67. The Decedent was prescribed and/or purchased and/or consumed and/or otherwise utilized the Defendants' devices for the purposes of controlling his blood glucose levels by way of an insulin pump and associated equipment. In so doing, Decedent relied upon

the skill, judgment, representations, and foregoing express written warranties of the Defendants. Said warranties and representations were false, misleading, and inaccurate in that the aforementioned product was defective and/or not in compliance with FDA regulations and/or did not conform to or perform in accordance with approved specifications and/or malfunctioned or failed to perform as intended during use and was not therefore safe and effective and was unfit for the uses for which it was intended or put with the knowledge and/or encouragement and/or approval of Defendants.

68. The Medtronic MiniMed Infusion Sets and MiniMed 630G Insulin Pump at issue did not conform to the Defendants' express representations and warranties.

69. At all relevant times, said products did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

70. At all relevant times, said products did not perform in accordance with the Defendants' representations.

71. As a direct and proximate consequence of the breach of express warranties by the Defendants, and each of them, Decedent after purchasing and/or consuming and/or ingesting and/or otherwise utilizing Defendants non-conforming and defective medical device, suffered injuries, sustained damages, and that ultimately led to his death all compensable under Nevada law. Decedent, and Plaintiff, who suffered injuries compensable under Nevada law due to the death of Decedent, hereby assert a claim for breach of express warranty pursuant to applicable Nevada law.

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FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against all Defendants, Does 1-20 and Roes 1-20)

72. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

73. At all times and places material hereto, Defendants, and each of them, impliedly warranted to Decedent and/or Decedent's physicians that said products were of merchantable quality, were manufactured and/or packaged and/or labeled in accordance with FDA regulations, complied with applicable FDA regulations and approved specifications and were safe, effective and fit for use for which they were intended or for other known or foreseeable uses.

74. Decedent and Plaintiff were unskilled in the research, design, and manufacture of the product and reasonably relied entirely on the skill, judgment and implied warranties of Defendants, and each of them, in being prescribed, purchasing, consuming, and otherwise using the 630G and accompanying devices.

75. The 630G was not designed and/or manufactured and/or packaged and/or labeled in accordance with FDA regulations, did not conform to or perform in accordance with approved specifications, and/or was otherwise defective and was not therefore not safe or effective for its intended, known or foreseeable uses not of merchantable quality, as warranted by Defendants in that they had the potential to malfunction and/or fail to function as intended and cause serious and permanent injuries, including death when used for their intended, known, and foreseeable uses.

76. As a result of the aforementioned breach of implied warranties by Defendants, Decedent and Plaintiff, after Decedent being prescribed and/or after purchasing and/or

consuming and/or otherwise using Defendants' non-conforming, defective products, suffered injuries and sustained damages compensable under the laws of the State of Nevada.

77. The Defendants' breaches of implied warranties, pursuant to Nevada law, proximately resulted in the damages sustained by the Decedent, including his death.

FIFTH CAUSE OF ACTION
CONSUMER PROTECTION
(Against all Defendants, Does 1-20 and Roes 1-20)

78. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

79. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers, and sellers of the 630G insulin infusion pump, and accompanying devices, which Defendants represented to be free from defects and fit for their intended or foreseeable purposes in conformance with FDA approvals and regulations.

80. Defendants advertised, labeled, marketed, and promoted their products, representing the quality to healthcare professionals, the FDA, Decedent, Decedent's treating physicians, and the public in such a way as to induce the product's purchase or use.

81. Defendants knew or should have known that their products did not or would not conform to Defendants' representations and promises because the product was defective.

82. Defendants concealed knowledge of the serious risks associated with the device, concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data, and concealed the fact that the devices were defective.

83. Defendants' representations, actions, and conduct regarding their devices were in or affecting commerce and were misleading.

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84. Defendants' actions and conduct, as alleged throughout this Complaint, constitute deceptive trade practices under Nevada Revised Statutes, Title 52, Chapter 598 et seq. and/or other applicable statutory provisions concerning deceptive trade practices or consumer fraud.

85. As a direct and proximate result of Defendants' deceptive and/or unfair conduct, in affecting commerce, Decedent and Plaintiff are entitled to recover damages from Defendants, pursuant to the provisions of the Nevada Deceptive Trade Practices Act ("NDTPA"), codified as NRS Chapter 598 et seq. and/or other applicable statutory provisions concerning deceptive trade practices and consumer fraud.

SIXTH CAUSE OF ACTION
SURVIVAL ACTION
(Against all Defendants, Does 1-20 and Roes 1-20)

86. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

87. Plaintiff brings a survival action for any and all losses or damages which accrued as a result of Defendants' non-conforming products prior to Decedent's death. Including, all causes of action alleged herein, punitive and exemplary damages, damages for pain and suffering, loss of probable support and companionship, society, comfort, and consortium.

SEVENTH CAUSE OF ACTION
WRONGFUL DEATH – NRS 41.085
(Against all Defendants, Does 1-20 and Roes 1-20)

88. The Plaintiff and Decedent incorporate by reference and reallege each and every allegation in this Complaint the same as though specifically set forth herein.

89. As alleged herein the Defendants' non-conforming product, the 630G MiniMed, and accompanying products wrongfully caused the death of the Decedent.

90. As a result of the aforementioned breaches and wrongful conduct by Defendants, and after Decedent being prescribed and/or after purchasing and/or consuming and/or otherwise using Defendants' non-conforming, defective products, suffered injuries and sustained damages and led to his death, all of which are compensable under the laws of the State of Nevada.

DAMAGES AS TO ALL CAUSES OF ACTION

91. Plaintiff and Decedent were injured as a direct and proximate result of the conduct and breaches of the Defendants, as aforesaid, for which compensation is required. Specifically, the Defendants' products caused the Decedent to experience extreme hypoglycemia, diabetic coma, and ultimately his death. Plaintiff, on behalf of Decedent and herself is seeking monetary damages in the form of:

a. Damages for past medical, hospital and drug bills for Decedent;

b. Damages companionship, society, comfort and consortium;

c. Damages for disfigurement, impairment and/or disability;

d. Damages for past and future mental anguish, grief or sorrow and emotional distress for Plaintiff;

e. Damages for loss of enjoyment of life;

f. Damages for all other losses, both economic and intangible, arising from the injuries as set out herein, all of which were proximately caused by the act/or omissions of the Defendants;

g. Punitive and exemplary damages; and

h. Any other relief which the Court deems just and proper under the circumstances.

92. Plaintiff reserves the right to prove the amount of damages at trial, in an amount to be determined by the jury.

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93. As set forth hereinabove, the Defendants' conduct exhibited gross negligence and a willful, wanton, and reckless disregard for the safety of the Decedent and others. As a result of the Defendants' conduct, alleged herein, they are liable for punitive damages and attorney's fees, all litigation expenses and associated costs of litigation, and any other damages allowed by Nevada law.

94. Plaintiff prays that exemplary and punitive damages be assessed against the Defendants in an amount sufficient to punish the Defendants for their wrongful conduct as well as deter like conduct in the future, and to serve as an example and warning to others, so as to encourage the Defendants and other companies to have due and proper regard for the rights of consumers and to protect the general public from future wrongdoing, pursuant to Nevada law.

JURY DEMAND

95. Plaintiff hereby demands a trial by jury in this case as to such issues so triable.

CONCLUSION & PRAYER

WHEREFORE, Plaintiff prays for judgment against Defendants, their "alternate entities," and each of them, as is hereinafter set forth.

The Decedent, ANDRE CARL ROGET, by and through Plaintiff, GLORIA JEAN ROGET, Individually and as Special Administrator and Heir to the Estate of ANDRE CARL ROGET, Deceased:

1. For DECEDENT's medical and related expenses according to proof
2. For DECEDENT's pain and suffering;
3. For DECEDENT's loss of income and income potential;
4. For exemplary or punitive damages according to proof;
5. For DECEDENT's reasonable attorney's fees

Plaintiff, GLORIA JEAN ROGET, Individually and as Special Administrator and Heir to the Estate of ANDRE CARL ROGET, Deceased:

1. For DECEDENT's medical and related expenses according to proof;

2. For PLAINTIFF's loss of income and income potential caused by DECEDENT's death, and for PLAINTIFF's loss of DECEDENT's financial support and financial contributions;

3. For damages for fraud according to proof;

4. For funeral and burial expenses caused by DECEDENT's death;

5. For PLAINTIFF's general damages according to proof, including damages for loss of love, companionship, comfort, affection, solace, moral support and/or society according to proof caused by DECEDENT's death;

6. For exemplary or punitive damages according to proof;

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7. For PLAINTIFF's cost of suit and reasonable attorney's fees herein;

8. For such other and further relief as the Court may deem just and proper, including costs.

DATED this 19th day of April, 2022.

[redacted]