

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY,  
PENNSYLVANIA

ELSIE FLORIAN,

Plaintiff,

vs.

OLYMPUS AMERICA, INC; OLYMPUS  
CORPORATION OF THE AMERICAS;  
and OLYMPUS MEDICAL SYSTEM  
CORP.,

Defendants.

CIVIL DIVISION

No. GD 15- 005127

**COMPLAINT IN CIVIL ACTION**

Code and Classification: 004

Filed on behalf of Plaintiff

Counsel of Record for this Party:

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**JURY TRIAL DEMANDED**

FILED IN COURT RECORDS  
CIVIL DIVISION  
ALLEGHENY COUNTY, PA

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**NOTICE TO DEFEND**

YOU HAVE BEEN SUED IN COURT. If you wish to defend against the claims set forth in the following pages, you must take action within TWENTY (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

**LAWYER REFERRAL SERVICE  
ALLEGHENY COUNTY BAR ASSOCIATION  
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Telephone: (412) 261-5555**

**IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY,  
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AND NOW, come the Plaintiff, ELSIE FLORIAN, by and through her attorneys, Brendan B. Lupetin, Esquire, and the law firm of Meyers Evans & Associates, LLC, and files the within Complaint in Civil Action, averring and in support thereof as follows:

**INTRODUCTION AND SUMMARY OF ACTION**

1. Olympus America, Inc., Olympus Corporation of the Americas, and Olympus Medical System Corporation ("Olympus") are in the business of manufacturing and selling medical devices including endoscopes, which are medical devices used in invasive medical procedures within the human body. In or about 2014, Olympus redesigned one of its endoscopes, the TJF-Q180V Duodenoscope ("Q180V Scope"). The Q180V Scope was designed and intended for repeated and recurrent use in multiple medical procedures, on different patients. After each use, the Q180V Scope necessarily requires cleaning and disinfecting – known as "reprocessing" – before it can be used on a new patient. A manufacturer of a medical device like

an endoscope, which is going to be used in multiple patients, has an obligation to develop and validate a reprocessing protocol, and to incorporate this protocol into the product's labeling.

2. The product labeling must provide sufficient instructions on how to prepare the device for the next patient use. The manufacturer must maintain in the Device Master Record and/or design history file as appropriate, documentation of tests that were performed to demonstrate that the instructions are complete and understandable and can reasonably be executed by the user. The device master record must comply with the requirements of 21 CFR 820.181; the design history file must comply with requirements of 21 CFR 820.30(j). The manufacturer must ensure that the validated reprocessing protocol is disseminated to medical facilities and professionals.

3. Olympus failed to take these critical steps with the redesigned Q180V Scope. Olympus failed to provide an effective and validated reprocessing protocol for the redesigned Q180V Scope. Instead, Olympus provided its customers – medical facilities and physicians – with a safety cleaning protocol for an older endoscope, with a significantly different design. As a result, end-users were not able effectively to sanitize and clean the new redesigned Q180V Scope.

4. As a direct result of Olympus's failure to develop and validate an effective reprocessing protocol for the redesigned Q180V Scope, the end-users exposed multiple patients to potentially contaminated Q180V Scopes. The end-users rely on the manufacturer of the scope to provide an effective and validated reprocessing protocol. It was unknown to the end-users that the old reprocessing protocol was not effective in removing all residual body fluids and organic debris from the device after use. These residual fluids and debris can contain microbial contamination. When microbial contamination remains on the device, the Q180V Scope is

contaminated. Any patient who underwent a medical procedure with a contaminated Q180V Scope was exposed to serious health risks including severe infection and death.

5. Plaintiff Elsie Florian was exposed to a contaminated Q180V Scope when she underwent multiple procedures with this device at Allegheny General Hospital between February 23, 2015 and March 4, 2015. As a result of the exposure to this contaminated device, Plaintiff suffered significant injury, including but not limited to, the contraction of a strain of carbapenem-resistant Enterobacteriaceae (CRE).

### **PARTIES**

6. Plaintiff Elsie Florian is a citizen of the State of Pennsylvania and resides at 12A Longfellow Drive, Homestead, Allegheny County, Pennsylvania 15120.

7. Defendant Olympus America, Inc., (hereafter "Olympus America") is a corporation organized and existing under the laws of the State of New York. Olympus America's principal place of business is 3500 Corporate Parkway, Center Valley, Lehigh County, Pennsylvania 18034. Olympus America maintains multiple offices in California, including an office at 10863 Holder Street, Cypress, California. Among its business activities, Olympus America sells, markets, and services Olympus medical products in the United States, including endoscopes including the specific Q180V Scope involved in the subject incident. At all times relevant to this action, Olympus America has conducted substantial business in Pennsylvania and regularly caused its products to be sold in Pennsylvania. One specific way in which Olympus America engages in the sales and marketing of its endoscopes in the County of Los Angeles is through its Endoscopy sales group that consists of, but is not limited to, Endoscopy Account Managers who are based in and conduct business in the Commonwealth of Pennsylvania. Furthermore, Plaintiff's causes of action arise out of a specific conduct committed in the County

of Allegheny, Commonwealth of Pennsylvania. Therefore, personal jurisdiction is proper under 42 Pa. Consol. Stat. Ann. § 5322 and the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States of America.

8. Defendant Olympus Corporation of the Americas (hereafter "Olympus Corp.") is a corporation organized and existing under the laws of the State of New York. Olympus Corp.'s principal place of business is 3500 Corporate Parkway, Center Valley, Lehigh County, Pennsylvania 18034. Among its business activities, Olympus Corp. is involved in the distribution, sales, marketing, regulatory management, and services related to Olympus medical products in the United States, including the specific Q180V Scope involved in the subject incident. At all times relevant to this action, Olympus Corp. has conducted substantial business in Pennsylvania. Plaintiff's causes of action arise out of a specific conduct committed in the County of Allegheny, Commonwealth of Pennsylvania. Therefore, personal jurisdiction is proper under 42 Pa. Consol. Stat. Ann. § 5322 and the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States of America.

9. Defendant Olympus Medical System Corporation (hereafter "Olympus Medical") is a foreign corporation organized and existing under the laws of Japan with its principal place of business located at Shinjuku Monolith, 2-3-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0914, Japan. Olympus Medical designs, manufactures, assembles, tests, markets, distributes, and sells medical endoscopes, including the specific Q180V Scope involved in the subject incident. Olympus Medical may be served by and through the Chairman of the Board, Chief Executive Officer, and President of Olympus Medical under Article 10(a) of the Hague Service Convention, to which Japan is a signatory, and as is consistent with Pennsylvania law. In addition, Olympus Medical may be served through Japan's central authority pursuant to Article 5

of the Hague Convention. At all times relevant herein, Olympus Medical conducted substantial business in Pennsylvania, regularly caused its products to be sold in Pennsylvania, and the cause of action arises out of a tort committed in Pennsylvania. Therefore, personal jurisdiction is proper under 42 Pa. Consol. Stat. Ann. § 5322 and the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States of America.

10. Defendants Olympus America, Olympus Corp., and Olympus Medical (hereafter, collectively, "Olympus") designed, developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Olympus endoscopes throughout the United States.

11. Olympus' Endoscopy sales group which advertised, marketed and/or sold the endoscopes and/or duodenoscopes herein complained of, was the representative, agent, employee, joint venturer, or alter ego of each of the other defendants and in doing the things alleged herein was acting within the scope of its authority as such.

### **GENERAL ALLEGATIONS**

12. Olympus manufactures and sells endoscopes to be used repeatedly by medical service providers in endoscopic retrograde cholangiopancreatography procedures ("ERCP"). Specifically, Olympus designs, manufactures, assembles, tests, markets, distributes, promotes, advertises and sells duodenoscopes, a sub-type of endoscope, to be used by medical practitioners for internal and invasive diagnostic and therapeutic procedures within a human's body, such as a person's hepatobiliary and pancreatic systems.

13. Olympus has known that the complex design of its duodenoscopes renders some parts of the medical device extremely difficult to access. As a result, effective cleaning of its duodenoscopes is difficult. Defendants have known that the moving parts of the elevator mechanism within the duodenoscope contain microscopic crevices that may not be reached with

a brush, and that residual body fluids and organic debris may remain in these crevices following use. Defendant knew, or should have known, that if these residual fluids contain microbial contamination, multiple patients would be exposed to a serious risk of harm, including lethal infection.

14. In 2014, Olympus completely redesigned the TJF-Q180V Duodenoscope, broadening the range of scope positions in which the device's guide wire can be securely locked.

15. Notwithstanding this complete redesign, Olympus failed to take any action to update the reprocessing protocol for the TJF-Q180V Duodenoscope (hereinafter "Q180V Scope"). Specifically, Defendants failed to: (a) re-evaluate the existing safety and cleaning/disinfection protocols developed for earlier duodenoscope models; (b) research and develop reliable safety and cleaning/disinfection protocols for the Q180V Scope prior to marketing the product; (c) provide purchasers and end-users with effective and validated cleaning/disinfection protocols for the Q180V Scope at the date of sale; (d) recall the Q180V Scope upon realizing that Olympus had not updated the safety and cleaning/disinfection protocols; and (e) provide purchasers and end-users with effective and validated cleaning/disinfection protocols for the Q180V Scope at any time after the date of sale.

16. Even before the redesign and subsequent sale and marketing of the Q180V Scope, Defendants were on notice that Defendants' endoscope devices were difficult to clean and, as such, that they posed health risks to patients exposed to the devices. In 2013, Olympus was informed of infections to patients in the state of Washington involving multiple duodenoscopes from its 160 and 180 series. At least four patients who were infected as a result of exposure to contaminated duodenoscopes died.



17. Despite the harm that can result from inadequately disinfected Q180V Scopes, Defendants negligently, recklessly, and with conscious disregard of the extreme risks to the public of serious infection, pain, suffering, and death, aggressively marketed and sold the Q180V Scope to medical service providers across the United States and in Pennsylvania, including Allegheny General Hospital (hereafter "AGH"), claiming that the product was a safe and effective device, that could be recurrently and invasively used in multiple patients for ERCP procedures.

18. A manufacturer of a medical device like an endoscope, which is going to be used in multiple patients, has an obligation to develop and validate an effective reprocessing protocol, and then to disseminate the protocol to medical facilities and professionals.

19. Defendants knew that end-users of the Q180V Scope relied on the manufacturer to provide effective and validated reprocessing protocols necessary for the safe operation of the Q180V Scope. Defendants intended and expected the Q180V Scope to be used invasively by medical service providers, in multiple patients across the United States. Defendants sold the Q180V Scope to AGH with that intention and expectation.

20. AGH, based on information and belief, complied with the reprocessing protocols provided by Defendants in its operation and use of the Q180V Scopes it purchased from Defendants. AGH, based on information and belief, complied with the reprocessing protocols provided by Defendants because Defendants represented those protocols as adequate and effective for the safe use and operation of the Q180V Scope.

21. The reprocessing protocols provided by Defendants, to be used in the operation of their Q180V Scope, were inadequate. Despite complying with the protocols which Defendants provided, and which Defendants instructed AGH to implement, on information and belief,

multiple patients, including Plaintiff, were infected with a highly drug-resistant bacteria. Specifically, as a direct and proximate result of an ERCP procedure using Defendants' Q180V Scope, each of these individuals, including Plaintiff, were infected with lethal drug-resistant bacteria.

22. As a direct and proximate result of Defendants' failure to update the reprocessing protocols for the Q180V Scope, and of their fraudulent marketing and sale of the device as safe and effective, multiple individuals, including Plaintiff, have suffered extraordinary pain and suffering, incurring both general and special damages to be proven at trial.

WHEREFORE, Plaintiff claims compensatory and punitive damages from Defendants in excess of the threshold amount of a board of arbitrators in this jurisdiction and demand a trial by jury.

**FIRST CAUSE OF ACTION**  
**(Products Liability Sounding in Negligence)**  
**Against All Defendants**

23. Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

24. Defendants designed, manufactured, promoted, distributed, marketed, and sold the Q180 V Scope.

25. At all times material hereto, the Q180V Scope, that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants, was expected to reach, and did reach, physicians and consumers, including Plaintiff, without substantial change to the condition in which it was sold.

26. At all times material hereto, the Q180V Scope that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants, was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

27. When placed in the stream of commerce, the Q180V Scope was designed in such a manner that it required a specific reprocessing protocol to render it safe for re-use in subsequent procedures on new patients. Olympus failed to provide an effective and validated reprocessing protocol for the Q180V Scope, thus rendering it unsafe for its intended use, and subjecting Plaintiff and others to risks;

28. The reprocessing protocol associated with the Q180V Scope was insufficiently tested, rendering that reprocessing protocol unsafe and, thus, rendering the Q180V Scope defective; and

29. Olympus failed to develop an effective and validated reprocessing protocol for the completely redesigned Q180V Scope, thus rendering the device defective.

30. The Q180V Scope has a unique design that renders it susceptible to microbial contamination no matter how the device is cleaned, thereby rendering the Q180V scope defectively designed.

31. Defendants knew or should have known of the dangers associated with the use of the Q180V Scope, as well as the fact that the existing reprocessing protocol was insufficient to disinfect the newly redesigned Q180V Scope. Notwithstanding this knowledge, Defendants continued to manufacture, sell, distribute, promote and supply the Q180V Scope so as to maximize sales and profits at the expense of the health and safety of the public. Defendants took

these actions in conscious disregard of the foreseeable harm caused by the Q180V Scope, and in conscious disregard for the rights and safety of consumers such as the Plaintiff.

32. The Plaintiff's physician used the Q180V Scope as directed for its intended purpose.

33. At all times herein mentioned, the Q180V Scope was defective, and Defendants knew that it was to be used without inspection for defects in the reprocessing protocol. Moreover, neither the Plaintiff nor Plaintiff's physicians knew, or had reason to know, at the time of the use of the subject products, of the existence of the aforementioned defects. Neither Plaintiff nor Plaintiff's physicians could have discovered the defects in the Q180V Scope through the exercise of reasonable care.

34. The Q180V Scope had not been materially altered or modified prior to its use in Plaintiff.

35. As a direct and proximate result of the exposure to the defective Q180V Scope, Plaintiff suffered injuries and damages as described herein.

WHEREFORE, Plaintiff claims compensatory and punitive damages from Defendants in excess of the threshold amount of a board of arbitrators in this jurisdiction and demand a trial by jury.

**SECOND CAUSE OF ACTION**  
**(Negligence)**  
**Against All Defendants**

36. Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

37. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the Q180V Scope, including a duty to ensure that the Q180V Scope did not pose a significantly increased risk of adverse events.

38. Defendants failed to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the Q180V Scope. Defendants knew, or should have known, that the Q180V Scope required a new reprocessing protocol unique to the Q180V Scope design and one which was effective and validated. Defendants knew that, if inadequately cleaned, the Q180V Scope posed a significant risk of contamination, giving rise to infection, and causing injury, pain, suffering, debilitation and subsequent medical treatment, with the attendant risks of serious injury or death, and therefore was not safe for use by Plaintiff.

39. Despite the fact that Defendants knew or should have known that the Q180V Scope lacked an adequate, effective and validated reprocessing protocol, which was suited to the device's new design and, that if inadequately cleaned, the Q180V Scope posed a significant risk of contamination, giving rise to infection, and causing pain and suffering, debilitation and subsequent medical treatment, with the attendant risks of serious injury or death, Defendants continued to market the Q180V Scope as a safe and effective device.

40. In so doing, the Defendants failed to act as a reasonable manufacturer and distributor of duodenoscopes.

41. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and will continue to suffer such damages in the future.

WHEREFORE, Plaintiff claims compensatory and punitive damages from Defendants in excess of the threshold amount of a board of arbitrators in this jurisdiction and demand a trial by jury.

**THIRD CAUSE OF ACTION**  
**(Fraud - Intentional Misrepresentation)**  
**Against All Defendants**

42. Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

43. Defendants owed legal duties to Plaintiff to disclose important material facts concerning the safety of the Q180V Scope and the adequacy of the reprocessing protocol for the Q180V Scope, to ensure it was disinfected and safe for reuse.

44. Defendants made false representations to Plaintiff and/or Plaintiff's physicians concerning the safety of the Q180V Scope and the risks associated with the reprocessing protocol for the Q180V Scope. Specifically, Defendants intentionally, knowingly, or recklessly without regard for the truth, misrepresented that the reprocessing protocol associated with the Q180V Scope was a safe and adequate means of cleaning and disinfecting the Q180V Scope. Defendants falsely represented that the Q180V Scope would be disinfected and safe for subsequent use in a new patient after undergoing cleaning pursuant to the reprocessing protocol. Defendants made those false representations in an effort to mislead consumers into purchasing the Q180V Scope and using it for medical procedures, so that Defendants could profit. Through their agents, Defendants directly communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were Plaintiff's fiduciaries.

45. Olympus sales force made the representations described above to physicians and staff at AGH prior to February 23, 2015.

46. At no time prior to the use of Defendants Q180V Scope in Plaintiff did Defendants acknowledge that the reprocessing protocol provided to AGH had not been validated and proven effective in disinfecting the redesigned Q180V Scope.

47. Defendants' representations to Plaintiff and/or Plaintiff's physicians were false because in reality the reprocessing protocol was not effective to adequately disinfect the Q180V Scope for re-use in a new patient. As such, the Q180V was unsafe for use. Defendants' reprocessing protocol did not eliminate all bodily fluids and organic debris from prior use, thereby rendering the Q180V Scope susceptible to microbial contamination. Defendants' reprocessing instructions did not prepare the Q180V Scope for safe re-use.

48. Defendants intended medical professionals, including Plaintiff's physicians, and patients to rely on the Defendants' the important material representations regarding the safety of the Q180V and adequacy of the reprocessing protocol.

49. Plaintiff and Plaintiff's physicians reasonably relied on Defendants' misrepresentations to Plaintiff's detriment. Plaintiff's physicians used a previously-used Q180V Scope on Plaintiff only after attempting to clean and disinfect the Q180V Scope following Defendants' reprocessing protocol. Following the reprocessing, Plaintiff and Plaintiff's physicians believed the Q180V Scope was safe for use on Plaintiff when, in fact, it was contaminated with bacteria.

50. As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured, thereby causing harm and damage to Plaintiff.

WHEREFORE, Plaintiff claims compensatory and punitive damages from Defendants in excess of the threshold amount of a board of arbitrators in this jurisdiction and demand a trial by jury.

**FOURTH CAUSE OF ACTION**  
**(Fraud - Negligent Misrepresentation)**  
**Against All Defendants**

51. Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

52. Defendants owed legal duties to Plaintiff to disclose important material facts concerning the safety of the Q180V Scope and the adequacy of the reprocessing protocol for the Q180V Scope in disinfecting the scope to ensure it is safe for reuse.

53. Defendants made false representations to Plaintiff and/or Plaintiff's physicians concerning the safety of the Q180V Scope and the risks associated with the reprocessing protocol for a previously used Q180V Scope. Defendants failed to develop an effective and validated reprocessing protocol for the redesigned Q180V Scope and/or failed to test the existing reprocessing protocol on the Q180V Scope and/or failed to adequately investigate prior complaints by medical facilities of contamination of Defendants' scopes, despite the fact that these devices had been reprocessed in accordance with the recommended protocol. Nevertheless, Defendants falsely represented that the Q180V Scope would be disinfected and safe for subsequent use in a new patient after administration of the reprocessing protocol. Defendants made those false representations in an effort to encourage consumers to purchase and use the Q180V Scope for medical procedures, so Defendants could profit. Through their agents,



Defendants directly communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were Plaintiff's fiduciaries.

54. Olympus sales force, made the representations described above to physicians and staff at AGH prior to February 23, 2015.

55. At no time prior to the use of Defendants Q180V Scope in Plaintiff did Defendants acknowledge that the reprocessing protocol provided to AGH had not been validated and proven effective in disinfecting the redesigned Q180V Scope.

56. Defendants' representations to Plaintiff and/or Plaintiff's physicians were false because in reality the reprocessing protocol was not effective to adequately disinfect the Q180V Scope for re-use in a new patient. As such, the Q180V was unsafe for use. Defendants' reprocessing protocol did not eliminate all bodily fluids and organic debris from prior use, thereby rendering the Q180V Scope susceptible to microbial contamination. Defendants' reprocessing instructions did not prepare the Q180V Scope for safe re-use.

57. Defendants intended medical professionals, including Plaintiff's physicians, and patients to rely on the Defendants' the important material representations regarding the safety of the Q180V and adequacy of the reprocessing protocol.

58. Plaintiff and Plaintiff's physicians reasonably relied on Defendants' misrepresentations to Plaintiff's detriment. Plaintiff's physicians used a previously-used Q180V Scope on Plaintiff only after attempting to clean and disinfect the Q180V Scope following Defendants' reprocessing protocol. Following the reprocessing, Plaintiff and Plaintiff's physicians believed the Q180V Scope was safe for use on Plaintiff when, in fact, it was contaminated with bacteria.

59. As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured, thereby causing harm and damage to Plaintiff.

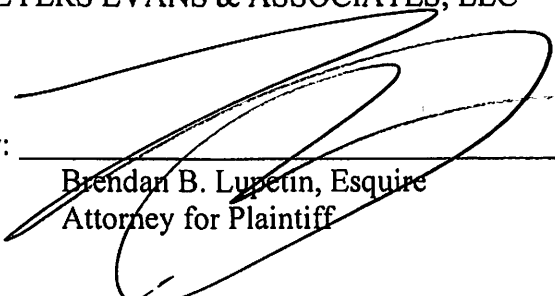
WHEREFORE, Plaintiff claims compensatory and punitive damages from Defendants in excess of the threshold amount of a board of arbitrators in this jurisdiction and demand a trial by jury.

**JURY TRIAL DEMANDED**

Respectfully submitted,

MEYERS EVANS & ASSOCIATES, LLC

By: \_\_\_\_\_

  
Brendan B. Lupetin, Esquire  
Attorney for Plaintiff

VERIFICATION

I, ELSIE FLORIAN, have read the foregoing **COMPLAINT IN CIVIL ACTION**. The factual information therein which was provided by me to my attorneys is true and correct to the best of my personal knowledge, information or belief.

Any other contents of the Complaint in Civil Action, including additional factual information, legal theories or conclusions of law, have been prepared by my attorneys, who have signed the pleading, and are based upon their investigation and analysis of information available to them and the applicable law.

I make this statement subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.

DATE: 3/27/2015

*Elsie Florian*  
ELSIE FLORIAN