UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

ARMANDO CUELLAR, ALEYDA ROMERO, individually and o/b/o their minor child, VALENTINA CUELLAR	*	**CIVIL ACTION:**
Plaintiffs	*	**SECTION:**
VERSUS	*	**JUDGE:**
LIVANOVA DEUTSCHLAND GmbH and LIVANOVA HOLDING, USA, INC	*	**MAGISTRATE:**
Defendants	*	

****

COMPLAINT

NOW INTO COURT, through undersigned counsel, come plaintiffs who file the within Complaint:

PARTIES

1.

The following plaintiffs bring this action:

A. Armando Cuellar, Aleyda Romero, individually and on behalf of their minor child, Valentina Cuellar, residents of Orleans Parish, State of Louisiana.

2.

The following parties are made defendant(s) in this action:

A. Defendant LivaNova Deutschland GmbH ("LivaNova"), formerly known as Sorin Group Deutschland GmbH, is a foreign for profit corporation headquartered in Munchen, Germany. LivaNova is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate

commerce, either directly or indirectly, numerous medical devices throughout the United States, including in the States of Louisiana and Pennsylvania.

B. Defendant LivaNova Holding USA, Inc., ("Sorin USA"), formerly known as Sorin Group USA, Inc., is a Delaware corporation with is principal place of business located at 14401 West 65th Way, Arvada, Colorado 80004.

3.

Jurisdiction is proper as the acts that give rise to the allegations occurred in this district and the plaintiffs reside in this district.

FACTS

4.

Defendants LivaNova and Sorin, USA are engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly, numerous medical devices, including the Sorin Heater-Cooler thermal regulator device ("Sorin Heater-Cooler"), throughout the United States, including in the State of Louisiana.

5.

At all material times, the Sorin Heater-Cooler was marketed and sold to hospitals in the State of Louisiana. In particular, the Sorin Heater-Cooler was sold by Sorin USA to Louisiana Children's Medical Center ("LCMC") in New Orleans, Louisiana.

6.

The Sorin Heater-Cooler is a cardiopulmonary bypass temperature controller.

7.

The Sorin Heater-Cooler is used to provide temperature-controlled water to heat exchanger devices, including cardiopulmonary bypass heat exchanges, cardioplegia heat exchangers, and thermal regulating blankets, used to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.

8.

On or about September 19, 2005, Sorin Group Deutschland GmbH submitted a §510(k) pre-market notification of intent to market the Sorin Heater-Cooler. See FDA §510(k) No. K052601.

9.

The §510(k) pre-market notification and approval process is regarded as a simplified application process that does not require an extensive review and approval by the United States Food and Drug Administration (FDA) because the entity applying for §510(k) approval certifies that the device is substantially equivalent to an already legally-marketed device.

10.

The §510(k) pre-market notification submitted by Sorin Group Deutschland GmbH states that the Sorin Heater-Cooler is substantially equivalent in safety and effectiveness as three predicate devices.

11.

In the pre-market notification submitted to the PDA, Sorin Group Deutschland GmbH certified that the Sorin Heater-Cooler "do[es] not raise new issues of safety or effectiveness."

12.

No clinical trials were conducted in connection with the submission of the Sorin Heater-Cooler §510(k) application process.

13.

On or about June 6, 2006, the FDA determined that the Sorin Heater-Cooler was substantially equivalent to legally marketed predicate devices and approved the marketing of the Sorin Heater-Cooler system.

14.

The FDA approved the Sorin Heater-Cooler as a Class II device.

15.

Thereafter, the Manufacturers began marketing and selling the Sorin Heater-Cooler with Instructions for Use ("IFU").

16.

At all times relevant hereto, Sorin Group Deutschland GmbH and/or Sorin USA was required to develop, test, and validate safe cleaning and disinfection protocols, and to incorporate these protocols into the Sorin Heater-Cooler device's labeling and IFU.

17.

The Sorin Heater-Cooler device's labeling and IFU must provide sufficient instructions on how to clean and disinfect the device, and the instructions or protocol must be validated by the manufacturer prior to the device being marketed, as per Title 21, Code of Federal Regulations, Part 820.

18.

Upon information and belief, LivaNova and/or Sorin USA's validation of the Sorin Heater-Cooler cleaning and/or disinfection procedures outlined in the IFU was conducted without considering the presence of mycobacteria. Further, upon information and belief, LivaNova and/or Sorin USA's IFU did not consider cleaning guidelines or disinfection protocols for water quality outside of Germany.

19.

On or about January 28, 2014, Sorin USA received a report from a health professional that one or more patients experienced an infection after surgeries in which the Sorin Heater-Cooler was used. The hospital's investigation found bacteria in the tanks of all Sorin Heater-Cooler devices at the facility.

20.

On or about February 12, 2014, Sorin USA filed a MAUDE Adverse Event Report with the FDA.

21.

On or about June 19, 2014, Sorin USA received a report from a user facility's risk manager that fifteen patients tested positive for an "atypical mycobacterium infection." Out of the fifteen patients who were identified as infected, four of them had died.

22.

On or about July 14, 2014, Sorin USA authored a letter entitled, "IMPORTANT INFORMATION Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices" (hereinafter "July 2014 'Important Information' letter").

23.

The July 2014 "Important Information" letter was sent "Attention: Hygiene Specialist, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

24.

The July 2014 "Important Information" letter states as follows:

"*We would like to bring to the attention of our customers a newly identified risk for cardiac surgery patients. Some cardiac surgery patients have been infected with a slow growing Mycobacterium chimaera….It is important to assure that your staff is aware of the Mycobacteria risk and to review your hygiene & surgical practices in the cardiac surgery theatre. This review should include your sampling and monitoring programs for your water sources, solution preparations and systems that use water in the cardiac surgery theatre. Among these water systems, heater cooler device(s) need strict adherence to the cleaning, disinfection and maintenance according to the operating manual….Without vigilant performance of the disinfection per the Operating Instructions, these organisms can multiply in a heater cooler device and potentially form biofilm….*"

25.

The July 2014 "Important Information" letter continues,

"*One of the highest risks of contamination for the patient is a direct contact transfer of water/solution droplets containing mycobacteria into the surgical field. Another risk that should be reviewed is the air distribution within the cardiac surgery theatre as this can be a transmission method for mycobacteria. The air conditioning as well as ventilation units including the heater cooler device fans needs to be considered in that analysis.*"

26.

The July 2014 "Important Information" letter also states:

"*During the investigation work it has been identified that some hospitals heater cooler devices are contaminated. By way of caution and as a safety measure, Sorin reminds its customers using heater cooler devices about the importance of adhering to the correct maintenance of the device at all times and in particular to assure that the cleanliness of the water in the device is maintained. If the water is not properly disinfected and maintained, microbiological growth can*

occur within the device and over time biofilm may form."

27.

The July 2014 "Important Information" letter states that "strict guidelines to the instructions is mandatory for the safe use of the device."

28.

The July 2014 "Important Information" letter also enclosed the Manufacturer Defendants' latest version of the operating instructions for the Sorin Heater-Cooler devices ("2014 IFU").

29.

According to Part 5.2 of the 2014 IFU, entitled, "Filling the water tanks," the "water tanks must be disinfected prior to operating the heater-cooler for the first time." Filtered tap water was to be used, and in order to prevent microbial growth, "100 ml of medical grade 3% hydrogen peroxide should be added to the filtered tap water." Every five days, 50 ml of hydrogen peroxide was to be added to the water tank, and the water "should be changed every two weeks."

30.

According to Part 6.2.1 of the 204 IFU, entitled, "Disinfection of the water circuits," "[t]he water circuits must be disinfected prior to operating the heater-cooler for the first time, when placing the unit in storage and if the hydrogen peroxide was not routinely performed. In order to prevent microbial growth, we recommend performing the disinfection cycle every 3 months."

31.

The disinfection procedure listed in Part 6.2.1 of the 2014 IFUs applies to the "water circuits," which includes the pump, heating and cooling tanks, fittings and all interconnecting tubing.

32.

Part 6.2.1 of the 2014 IFU states, "[f]or disinfection of the water circuits, use Clorox® Regular-Bleach, Maranon or another SORIN GROUP approved disinfectant."

33.

On or about April 7, 2015, a laboratory contracted by the Manufacturer Defendants completed testing designed to evaluate the effectiveness of the Sorin Heater-Cooler's updated disinfection procedures in eliminating various bacteria, including mycobacteria chimaera.

34.

According to a White Paper authored by Sorin USA, "[w]ith the enhanced hygiene concept, it is possible to achieve a bacterial count lower than 100 CFU/ml and no mycobacteria in the water of the 3T heater-cooler."

35.

Sorin USA's White Paper specifically notes that its test results, which demonstrated the efficacy of its "expanded hygiene concept," were limited to new devices only. The White Paper states as follows:

> "*Note: all of the above results have been obtained on a new device released from production. This means that the initial level of bacterial contamination was limited, and specifically, that no biofilm or any other environment favorable to bacterial growth was present. The efficacy of the same disinfectant on a highly contaminated device could not be demonstrated….*" (emphasis added).

36.

Upon information and belief, by April 2015, Sorin USA knew that their "enhanced hygiene concept" was ineffective in eliminating all bacteria, including mycobacteria chimaera, from devices that were not new and/or were already contaminated.

37.

On or about April 30, 2015, the European Centre for Disease Prevention and Control Issued a Rapid Risk Assessment, which linked cardiac surgery-associated mycobacterium chimaera infections to heater-cooler units.

38.

According to Sorin USA, in May 2015, they set up a "deep disinfection service" at Sorin Group Deutschland facilities, after realizing that "existing disinfection procedures would not be sufficient to reduce the risk of bacterial contamination of a heater-cooler device if it had not been properly maintained (according to IFU) for a long period of time, thus allowing a biofilm to grow in the water circuit."

39.

On or about June 3, 2015, Sorin USA authored a Field Safety Notice entitled, "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices."

40.

The June 3, 2015, Field Safety Notice was sent "Attention: Hygiene Specialist, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

41.

The June 3, 2015 Field Safety Notice states as follows:

> *"Sorin has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination."*

42.

The June 3, 2015, Field Safety Notice also provides customers with updated Instructions for Use regarding disinfection and maintenance procedures.

43.

On or about June 11, 2015, the United Kingdom's Medicines and Healthcare Products Regulatory Agency issued a Medical Device Alert warning of the risk of mycobacterium infection in patients undergoing cardiac surgery, associated with heater-coolers used with cardiopulmonary bypass machines.

44.

One or about June 15, 2015, Sorin USA authored a Field Safety Notice entitled, "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices."

45.

The June 15, 2015, Field Safety Notice was sent "Attention: Hygiene Specialist, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

46.

The June 15, 2015, Field Safety Notice states as follows:

> *"Sorin has become aware that the actual disinfection practices and its water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination."*

47.

The June 15, 2015 Field Safety Notice also provided customers with updated Instructions for Use, dated February 2015, regarding disinfection and maintenance procedures.

48.

On or about August 6, 2015, Sorin USA authored a letter, entitled, "Update to the Field Safety Notice for Heater-Cooler System 3T."

49.

According to the letter, "The Heater-Cooler System 3T Operating Instructions provided with the Field Safety Notice dated June 15, 2015, were intended for distribution

to English speaking countries in the European Union (EU) rather than for the United States."

50.

Attached to the August 6, 2015, letter were the updated Instructions for Use for devices used in the United States ("2015 IFU").

51.

According to Part 5.2 of the 2015 IFU, entitled, "Filling the water tanks," filtered tap water was to be used, and in order to prevent microbial growth, "150 ml (5 US Fl. Oz.) of medical grade 3% hydrogen peroxide solution" was to be added to the tank contents.

52.

According to Part 6.3 of the 2015 IFU, entitled, Disinfection of the water circuits," "[p]rior to operating the heater-cooler for the first time, when placing the system in storage and during regular operation, the water circuits must be disinfected at intervals of 14 days. The Heater-Cooler 3T water circuits include the pump, heating and cooling tanks, fittings and all interconnecting tubing."

53.

Part 6.3.1 of the 2015 IFU states, "[f]or disinfection of the water circuits, use Clorox Regular Bleach (active ingredient: 8.25% sodium hypochlorite), Minncare Cold Sterilant or another SORIN GROUP approved disinfectant."

54.

According to Part 6.3.1 of the 2015 IFU, either 6 fluid ounces of concentrated Clorox Regular Bleach or 15 fluid ounces of Minncare Cold Sterilant must be added to the Sorin Heater-Cooler's water tank to properly disinfect the device.

55.

According to Part 6.4 of the 2015 IFU, entitled, "Changing the water," "[t]he water in the water circuits must be changed every 7 days. In order to prevent microbial growth, add 150ml (5 US fl. Oz.) of medical grade 3% hydrogen peroxide solution to the tank contents."

56.

According to Sorin USA's "FAQs for the Heater-Cooler System 3T Disinfection Process," Sorin USA recommend water testing immediately and then every three weeks for units that were not properly maintained. Sorin USA also recommended implementing a monthly water testing schedule for units that were properly maintained.

57.

In July 2015, the Bavarian Health and Food Safety Authority conducted an on-site investigation of LivaNova's Munchen, German manufacturing facility. Environmental samples were taken from the production line, on-site tap water, and from a used and disassembled heater-cooler device in the manufacturer's service center. Six of twenty samples obtained were positive for mycobacteria chimaera.

58.

On or about October 15, 2015, the FDA issued a Safety Communication waring hospitals and health care professionals of the association between heater-cooler devices and nontuberculous mycobacterium ("NTM") infections.

59.

On or about October 21 and 27, 2015, the CDC issued two communications to raise awareness among healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

60.

On or about December 11, 2015, the Pennsylvania Department of Health issued a Health Advisory on NTM infections among patients undergoing open-heart surgeries.

61.

According to the Health Advisory, "epidemiological and microbiological findings from investigations in Europe and Pennsylvania convincingly support the conclusion that exposure to contaminated HCUs [heater-cooler units] is associated with NTM infection among patients undergoing open heart surgery on CPB (cardiopulmonary bypass]."

62.

On or about December 29, 2015, the FDA sent LivaNova a Warning Letter, after conducting inspections at the Manufacturers Defendants' Munchen and Arvada facilities. LivaNova is the parent company of Sorin USA.

63.

According to the Warning Letter, the inspections revealed that the Sorin Heater-Cooler devices are adulterated under 21 U.S.C.§ 351(h) and misbranded under 21 U.S.C. § 352(o) and (t)(2).

64.

According to the Warning Letter, the FDA advised LivaNova that its failure to validate the Sorin Heater-Cooler design changes to ensure the device's safety resulted in the device being illegally marketed.

65.

A Class II recall of the Sorin Heater-Cooler device was issued on March 17, 2016. The recall covers 1,125 units.

66.

The FDA "determined cause" for the recall is "device design."

67.

On April 28, 2016, an article entitled, "Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016" (hereinafter "Haller article") was published in the journal, Eurosurveillance.

68.

The Haller article presented the results of a surveillance of clinical cases and of contaminated heater-cooler devices, as well as environmental investigations in Germany prior to February 2016.

69.

According to the Haller article, "[d]uring environmental investigations, *M. chimaera* was detected in samples from used HCUs [heater-cooler units] from three different countries and samples from new HCUs as well as in the environment at the manufacturing site of one manufacturer in Germany." The manufacturing facility identified was the Manufacturers' facility in Munchen, Germany.

70.

The Haller article concluded that "at least some of the five German cases with M. chimaera infection may have occurred due to contamination of the HCUs by *M. chimaera* at the manufacturing site."

71.

Further, the Haller article notes, "[a]ccording to the information provided by the [Manufacturer Defendants], HCUs manufactured before mid-August 2014 may have had environmental mycobacteria presence in the unit at the time of delivery."

72.

On or about June 1, 2016, the FDA issued a Safety Communication entitled, "Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Sorin Heater-Cooler Heater-Cooler System."

73.

The FDA's Safety Communication notes that "[t]esting conducted by the manufacturer [Manufacturers] in August 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility."

74.

Accordingly to the FDA, the Haller article suggest "a direct link between the *M. chimaera* to which the European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model-the 3T."

75.

The FDA alerted health care facilities that if they purchased and used the 3T prior to September 2014, they must "be aware the units may have been shipped from the factory contaminated with *M. chimaera*."

76.

On October 13, 2016, the Center for Disease Controls issued a press release warning hospitals about the risk of Mycobacterium infections when using the Sorin Heater-Cooler.

77.

In the October 13, 2016 press release, the Center for Disease Controls specifically warned the hospitals to check to see what equipment was in use, ensure that they are maintained according to the latest manufacturer instructions, and alert affected patients and the clinicians who care for them.

78.

In response to the October 13, 2016 Center for Disease Controls press release, LivaNova, the parent company of Sorin USA, issued another Field Safety Notice Update that specifically noted that the Centers for Disease Control and the Federal Drug Administration recommended:

-Heater-cooler devices known or suspected to be contaminated with [Mycobacterium], based on the facility's testing program or other information known to the hospital, should be removed from service.

- Heater-cooler devices manufactured before September 2014 should only be used as directed by the FDA Safety Communication.

- Heater-cooler devices that are not known or suspected to be contaminated and manufactured during or after September 2014 should be used in accordance with the Operating Instructions and take into account additional precautions specified in the FDA Safety Communication.

a. Following the Operating Instructions for heater-cooler devices and specifically those relating to cleaning and disinfecting. We continue to believe that following these operating instructions is essential to mitigating the potential risk posed by using these non-sterile devices. The FDA Safety Communication confirms the importance of following the applicable operating instructions.

b. Conducting water quality monitoring per LivaNova's June 2015 3T Field Safety Notice "Cardiac Surgery Mycobacterium Risks."

79.

On December 2, 2016, LivaNova sent a letter asking facilities to review the November 1, 2016 recommendations from the FDA regarding the Sorin Heater-Cooler.

80.

LCMC owned and used Sorin Heater-Cooler devices during open-heart surgeries performed on Valentina Cuellar in August and September of 2017.

81.

After the open-heart surgeries performed on the minor Valentina Cuellar, in August and September of 2017, Valentina Cuellar was treated for *mycobacterium abscessus and staphylococcus aureus.*

82.

Upon information and belief, defendants' actions and inactions in marketing, design, construction, and failure to warn of the hazards of the Sorin Heater-Cooler led to damages by these plaintiffs.

83.

Upon information and belief, defendants could have taken steps to ensure that these patients would not have suffered damages from infection.

84.

Defendants are liable to the plaintiffs for violations of the Louisiana Products Liability Act for defendants' actions/inactions in the following non-particulars:

A. Developing, designing, manufacturing, testing, marketing, distributing, and selling a product that was unreasonably dangerous in design;

B. Developing, designing, manufacturing, testing, marketing, distributing, and selling a product that was unreasonably dangerous in construction or composition;

C. Failure to warn of the dangers of the use of the Sorin Heater-Cooler;

D. Failure to ensure safe use of the Sorin Heater-Cooler;

E. Failure to ensure that the Sorin Heater-Cooler did not exhaust in a manner that could cause infection;

F. Failure to manufacture the Sorin Heater-Cooler to avoid an unreasonable risk of harm;

G. Inadequate design;

H. Developing, designing, manufacturing, testing, marketing, distributing, and selling a product that was unreasonably dangerous because the product did not conform to an express warranty of the manufacturer about the product;

I. Breach of other duties that a medical device manufacturer owes a patient in a similar circumstance.

DAMAGES

85.

The damages to Plaintiffs were directly and proximately caused by the negligent acts and/or omissions of the Defendant(s), in the following non-exclusive particulars:

A. Past, present, and future physical pain and suffering;

B. Past, present, and future medical expenses;

C. Costs associated with the additional medical treatment;

D. Permanent scarring;

E. Mental anguish;

F. Emotional distress;

G. Lost wages;

H. Permanent impairment;

I. Loss of society and consortium;

J. Loss of enjoyment of life;

K. Such other damages as shall be discovered.

WHEREFORE Plaintiffs requests that the Defendants be duly cited and served with a copy of this petition and required to answer same and that, after due proceedings, there be a judgment in Plaintiffs' favor for all remedies allowed by law including judicial interest from the date of judicial demand.

Respectfully submitted,
CAPITELLI AND WICKER
By: s/T. Carey Wicker, III
T. Carey Wicker, III La. Bar No. 13450
J. Alex Watkins, La. Bar No. 29472
Vincent E. Odom, La. Bar No. 36918
1100 Poydras Street, Suite 2950
New Orleans, Louisiana 70163
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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

ARMANDO CUELLAR, ALEYDA ROMERO, individually and o/b/o their minor child, VALENTINA CUELLAR

(b) County of Residence of First Listed Plaintiff NEW ORLEANS
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
T. Carey Wicker, III, J. Alex Watkins, Vincent E. Odom
Capitelli and Wicker, 1100 Poydras St., Suite 2950, New Orleans, Louisiana 70163 Phone 504-582-2425

DEFENDANTS

LIVANOVA DEUTSCHLAND GMBH and LIVANOVA HOLDING USA, INC

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☒ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☒ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	**PERSONAL INJURY** ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Medical Malpractice	**PERSONAL INJURY** ☒ 365 Personal Injury - Product Liability ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability **PERSONAL PROPERTY** ☐ 370 Other Fraud ☐ 371 Truth in Lending ☐ 380 Other Personal Property Damage ☐ 385 Property Damage Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881 ☐ 690 Other **LABOR** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Management Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Employee Retirement Income Security Act	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 **PROPERTY RIGHTS** ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 840 Trademark **SOCIAL SECURITY** ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 400 State Reapportionment ☐ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities/ Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes
REAL PROPERTY	**CIVIL RIGHTS**	**PRISONER PETITIONS**	**IMMIGRATION**	**FEDERAL TAX SUITS**	
☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/ Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	**Habeas Corpus:** ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty **Other:** ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement	☐ 462 Naturalization Application ☐ 465 Other Immigration Actions	☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332

Brief description of cause:
Injuries caused by defective product

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Hon. John E. Jones, III DOCKET NUMBER MDL 2816

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

ARMANDO CUELLAR, ALEYDA ROMERO, individually and o/b/o their minor child, VALENTINA CUELLAR

Plaintiff(s)

v.

LIVANOVA DEUTSCHLAND GMBH and LIVANOVA HOLDING USA, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* LIVANOVA HOLDING USA, INC.
14401 West 65th Way
Arvada, Colorado 80004

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: T. Carey Wicker, III, J. Alex Watkins, Vincent E. Odom
Capitelli and Wicker
1100 Poydras St., Suite 2950
New Orleans, Louisiana 70163

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset