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Donna Jerry  
Health Care Administrator  
Green Mountain Care Board  
114 State Street  
Montpelier, VT 05620

Dear Ms. Jerry,

I am writing to request a Jurisdictional Determination by the Board for the following project described below, a 10,550 SF end cap space, located at Shelburne Road Shopping Plaza, 555-595 Shelburne Road, Burlington, VT.

Grifols would like to open its newest Biomat USA plasma donor center in the City of Burlington. Plasma, the liquid portion of blood, donated at Biomat plasma donor centers is used by Grifols to produce life-saving medicines that treat people with rare and chronic conditions. To meet the growing demand for plasma medicines, Grifols operates 252 plasma donor centers in 38 states.

Plasma that is collected contains hundreds of essential proteins and antibodies vital to the body's ability maintain critical functions. Without enough of one of these proteins, a person could have a life-threatening illness. Many of our patients depend on plasma medicines for their entire lives and it is their only treatment option. Every donation is important because it takes anywhere from 130 to 1200 donations to treat just one patient for one year.

The plasma donation process is similar to blood donation with some key differences. The first plasma donation can take over two hours and includes a physical exam, comprehensive medical screening and testing, and verification of donor identification and proof of physical address. Return donations typically take less than 90 minutes and also include a donor health screening, including vital signs,, donor verification and testing. Once a donor passes all of the screening, they then undergo the plasmapheresis process. Plasmapheresis is a specialized donation procedure using machines that separate plasma from whole blood, collects the plasma, while returning the rest of the blood back to the donor.

Because plasma is mostly water, the body regenerates plasma very quickly so regulations allow individuals to donate plasma as frequently as twice in a seven day period, with a full day in between donations. Plasma donation is a commitment, both in time and frequency so we compensate donors as thank you for their time.

All donors are screened prior to each of their donations. The screening includes blood pressure, temperature, weight, red blood cell count and hematocrit levels. Additionally, all plasma donations are screened for HIV, hepatitis B and hepatitis C using nucleic amplified testing (NAT), a state-of-the-art testing method that tests for the DNA particles of the virus. Each donation is also tested using a serological test that looks for antibodies the body produces in response to a virus.

Individuals that test positive for transmissible diseases are immediately referred to a physician or clinic for formal medical diagnoses testing and treatment. Their plasma is immediately destroyed and, if the donor has donated previously, a lookback is done to pull and destroy any previous donations. The donor is permanently deferred and excluded from ever donating

plasma as well as added to a National Donor Deferral Registry. Donors are checked against this national database of individuals who have been permanently rejected as donors in any U.S. plasma donor centers, including Grifols', as a result of positive test results.

Plasma donor centers are subject to multiple layers of regulatory oversight. Grifols centers are both licensed by the US Food and Drug Administration (FDA) and approved by European authorities. The regulatory agencies control all aspects of plasma and donor safety including how donors are screened and tested. The FDA and European authorities regularly inspect all Grifols plasma centers to verify compliance with quality assurance requirements and screening and testing protocols.

Depending on the importation country for final products; we receive inspections from European Authorities (EU) coordinated by European Medicines Agency (EMA) or the German Regierungspräsidium Darmstadt (Regional Council Darmstadt) (RPDA). Grifols also follows requirements of the Council of Europe/ European Pharmacopoeia and EU Directives. Grifols has a centralized Plasma Master File in EU, with Instituto Grifols as the license holder. Grifols intention is to have all centers as part of the EU Plasma Master File. It takes up to three years to add new centers to the EU Plasma Master File from the time a new center is opened.

All Grifols plasma centers are also inspected and certified by the voluntary industry standards body called the International Quality Plasma Program (IQPP) that conducts regular inspections of plasma donor centers to verify adherence to IQPP quality and safety standards. US state health and Clinical Laboratory Improvement Amendments (CLIA) officials inspect plasma centers to verify compliance with certain US state laws and laboratory testing procedures. Finally, Grifols has a robust internal regulatory program that routinely inspects and verifies internal quality requirements.

Because plasma donation is a commitment, we compensate donors as a thank you for their time. Donor fees vary depending on if the donor is a new donor (only been donating with us less than a month) or a return donor. The fees also depend on how frequently an individual donates. For new donors who donate the maximum frequency may receive anywhere from \$300 to \$500 a month based on time of year they start donating. Return donor, donating the maximum frequency, typically receive an average between \$275 and \$450 a month.

Grifols initial investment for the proposed plasma donor center site in Burlington, VT will take about a year and be around \$2.0 million for the construction of the plasma donor center plus another 500K to equip the center. Once we are fully operational, we will contribute approximately \$3.5 million each year to the local economy through payroll, donor fees and operating expenses.

The recruitment area for the center will likely be established at about a 20 to 30 mile radius, but could be set up to 100 miles if we find interest from other communities. All donors must have a permanent address living in our donor recruitment area and cannot reside in temporary housing such as hotels, shelters, or halfway houses. With Burlington being closer to the Canadian border, Canadian residents within the established range would be welcome to donate. The center will determine whether they will take donors based on an appointment system or walk-ins. Many centers do a mix of the two.

Grifols is proud to offer full-time positions that range needing just a high school diploma to more advanced degrees. All positions provide competitive salaries and full benefits, including 401K and paid time off. Additionally, all employees have the opportunity to progress their careers through robust training programs and continued education opportunities, such as advanced

education towards a college degree in partnership with the College for America or the Grifols tuition assistance program. Employees are able to progress their careers at Grifols, while knowing that they are helping save lives.

To start, the Burlington center will employ about 25 people from the surrounding area that will increase as the center grows. Employee numbers vary based on the number of donations, but the expectation is that the number of employees will grow to 35 in year two and 45-50 in year three. This number does not include contract vendors for items such as medical coverage, janitorial services, refrigeration services, landscaping and snow removal, and other routine maintenance.

On average these are the positions with in the center to start:

<b>Title</b>	<b>Degree</b>	<b>Number of Positions</b>
ASSISTANT MANAGER	Bachelor's degree or equivalent	1
CENTER MANAGER	Bachelor's degree or equivalent	1
CENTER QUALITY MANAGER	Bachelor's degree or equivalent	1
TRAINING COORDINATOR	Trained on site	1
MEDICAL OPER SUPR	Licensed	1
OPERATIONS SUPERVISOR	Trained on site	2
CENTER MEDICAL SPECIALIST	Licensed (RN/LPN/LVN/EMT/Paramedic)	8
MEDICAL SUPPORT TECHNICIAN	Licensed (RN/LPN/LVN/EMT/Paramedic)	2
LEAD PHLEBOTOMIST	Trained on site	1
LEAD DONOR CENTER TECHNICIAN	Trained on site	1
LEAD PHLEBOTOMIST	Trained on site	1
PHLEBOTOMIST	Trained on site	8
PLASMA PROCESSOR	Trained on site	2
DONOR CENTER TECHNICIAN	Trained on site	10
QUALITY ASSOCIATE	Trained on site	2
CENTER MEDICAL DIRECTOR – CONTRACT	Licensed	1

As part of our local commitment, Grifols also takes pride in being a good neighbor and strong community partner. Our centers give back to their communities through partnering with local organizations such as the United Service Organizations (USO) to help support our women and men in uniform, as well as supporting local foodbanks in our annual food drive campaign, which raised over 250,000 pounds of food in 2019. We plan to establish similar community relationships in Burlington to help make a meaningful impact in the community.

We continue to closely monitor the impact of the COVID-19 pandemic and will continue to follow the guidance that is communicated by the health authorities. Patients continue to need plasma medicines even during this time so our centers remain open. In fact, plasma donation and donors are considered within the category of essential, critical infrastructure that supports the healthcare system and is exempted from any of the stay at home guidelines according to the U.S. Department of Homeland Security.

The health and safety of all of our employees and donors is Grifols' top priority. We have implemented protocols as recommended by the Centers for Disease Control and Prevention (CDC) to prevent the spread of COVID-19 . We are limiting the limiting the number of donors in our centers by taking more appointments, seating donors every other donation bed and temporarily reducing the number of available seats in the lobby. We are also enhancing existing cleaning protocols, monitoring employee and donor temperatures, and following guidelines on hand hygiene. Importantly, we ask that donors and employees only come to one of our centers if they feel well and are healthy.

Thank you for your considerations and we look forward to providing members of the Burlington community the opportunity to donate plasma, help save lives and support Grifols mission of helping people in Vermont and around the world. If you have any questions or would like to discuss our development plan further please contact me at [Vlasta.hakes@grifols.com](mailto:Vlasta.hakes@grifols.com).

Best regards,



Vlasta Hakes  
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