
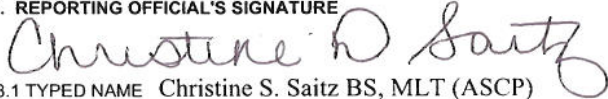


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 3000204209 CFN: 1835281 2. U.S. LICENSE NUMBER 248	3. REASON FOR SUBMISSION .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY 																																																																																																																																																																																																																																						
PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.		This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 333(a)).																																																																																																																																																																																																																																							
ENTER ALL CHANGES IN RED INK AND CIRCLE. 4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code) South Bend Medical Foundation, Inc. 118 W. Edison Road Mishawaka, IN 46545-3143 4.1 PHONE 574-273-8879 x1276		9. TYPE OF OWNERSHIP .1 <input type="checkbox"/> SINGLE PROPRIETORSHIP .2 <input type="checkbox"/> PARTNERSHIP .3 <input checked="" type="checkbox"/> CORPORATION profit <input type="checkbox"/> non-profit <input checked="" type="checkbox"/> .4 <input type="checkbox"/> COOPERATIVE ASSOCIATION .5 <input type="checkbox"/> FEDERAL (non-military) .6 <input type="checkbox"/> U.S. MILITARY .7 <input type="checkbox"/> STATE .8 <input type="checkbox"/> COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 <input type="checkbox"/> OTHER (Specify): _____		10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) .1 <input type="checkbox"/> COMMUNITY (NON-HOSPITAL) BLOOD BANK .2 <input type="checkbox"/> HOSPITAL BLOOD BANK .3 <input type="checkbox"/> PLASMAPHERESIS CENTER .4 <input type="checkbox"/> PRODUCT TESTING LABORATORY a. <input type="checkbox"/> INDEPENDENT <input type="checkbox"/> ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 <input type="checkbox"/> HOSPITAL TRANSFUSION SERVICE a. <input type="checkbox"/> APPROVED FOR MEDICARE REIMBURSEMENT <input type="checkbox"/> NOT APPROVED FOR MEDICARE REIMBURSEMENT .6 <input type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input checked="" type="checkbox"/> COLLECTION FACILITY } 248 .8 <input type="checkbox"/> DISTRIBUTION CENTER } U.S. LICENSE NUMBER OF PARENT FIRM .9 <input type="checkbox"/> BROKER/WAREHOUSE .10 <input type="checkbox"/> OTHER (Specify): _____																																																																																																																																																																																																																																					
5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.) The Medical Foundation		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">11. PRODUCTS</th> <th style="text-align: center;">COLLECT</th> <th style="text-align: center;">MANUAL APHERESIS</th> <th style="text-align: center;">AUTOMATED APHERESIS</th> <th style="text-align: center;">PREPARE</th> <th style="text-align: center;">LEUKOCYTES REDUCED</th> <th style="text-align: center;">IRRADIATED</th> <th style="text-align: center;">DONOR RETESTED</th> <th style="text-align: center;">TEST</th> <th style="text-align: center;">STORE and DISTRIBUTE to OTHERS</th> </tr> <tr> <th style="text-align: center;"> <input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED </th> <th style="text-align: center;">(-1)</th> <th style="text-align: center;">(2)</th> <th style="text-align: center;">(3)</th> <th style="text-align: center;">(4)</th> <th style="text-align: center;">(5)</th> <th style="text-align: center;">(6)</th> <th style="text-align: center;">(7)</th> <th style="text-align: center;">(8)</th> <th style="text-align: center;">(9)</th> </tr> </thead> <tbody> <tr><td>WHOLE BLOOD</td><td style="text-align: center;">1</td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RED BLOOD CELLS (RBC)</td><td style="text-align: center;">2</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC FROZEN</td><td style="text-align: center;">3</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC DEGLYCEROLIZED</td><td style="text-align: center;">4</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED</td><td style="text-align: center;">5</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED FROZEN</td><td style="text-align: center;">6</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED DEGLYCEROLIZED</td><td style="text-align: center;">7</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>CRYOPRECIPITATED AHF</td><td style="text-align: center;">8</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLATELETS</td><td style="text-align: center;">9</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>LEUKOCYTES/GRANULOCYTES</td><td style="text-align: center;">10</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA</td><td style="text-align: center;">11</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA CRYOPRECIPITATE REDUCED</td><td style="text-align: center;">12</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>FRESH FROZEN PLASMA</td><td style="text-align: center;">13</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>LIQUID PLASMA</td><td style="text-align: center;">14</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>THERAPEUTIC EXCHANGE PLASMA</td><td style="text-align: center;">15</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE LEUKOCYTES</td><td style="text-align: center;">16</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE PLASMA</td><td style="text-align: center;">17</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RECOVERED PLASMA</td><td style="text-align: center;">18</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD PRODUCTS FOR DIAGNOSTIC USE</td><td style="text-align: center;">19</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD BANK REAGENTS</td><td style="text-align: center;">20</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>OTHER</td><td style="text-align: center;">21</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>		11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS	<input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED	(-1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	WHOLE BLOOD	1	X								RED BLOOD CELLS (RBC)	2		X							RBC FROZEN	3									RBC DEGLYCEROLIZED	4									RBC REJUVENATED	5									RBC REJUVENATED FROZEN	6									RBC REJUVENATED DEGLYCEROLIZED	7									CRYOPRECIPITATED AHF	8									PLATELETS	9		X							LEUKOCYTES/GRANULOCYTES	10									PLASMA	11									PLASMA CRYOPRECIPITATE REDUCED	12									FRESH FROZEN PLASMA	13		X							LIQUID PLASMA	14									THERAPEUTIC EXCHANGE PLASMA	15									SOURCE LEUKOCYTES	16									SOURCE PLASMA	17									RECOVERED PLASMA	18									BLOOD PRODUCTS FOR DIAGNOSTIC USE	19									BLOOD BANK REAGENTS	20									OTHER	21								
11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS																																																																																																																																																																																																																																
<input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED	(-1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)																																																																																																																																																																																																																																
WHOLE BLOOD	1	X																																																																																																																																																																																																																																							
RED BLOOD CELLS (RBC)	2		X																																																																																																																																																																																																																																						
RBC FROZEN	3																																																																																																																																																																																																																																								
RBC DEGLYCEROLIZED	4																																																																																																																																																																																																																																								
RBC REJUVENATED	5																																																																																																																																																																																																																																								
RBC REJUVENATED FROZEN	6																																																																																																																																																																																																																																								
RBC REJUVENATED DEGLYCEROLIZED	7																																																																																																																																																																																																																																								
CRYOPRECIPITATED AHF	8																																																																																																																																																																																																																																								
PLATELETS	9		X																																																																																																																																																																																																																																						
LEUKOCYTES/GRANULOCYTES	10																																																																																																																																																																																																																																								
PLASMA	11																																																																																																																																																																																																																																								
PLASMA CRYOPRECIPITATE REDUCED	12																																																																																																																																																																																																																																								
FRESH FROZEN PLASMA	13		X																																																																																																																																																																																																																																						
LIQUID PLASMA	14																																																																																																																																																																																																																																								
THERAPEUTIC EXCHANGE PLASMA	15																																																																																																																																																																																																																																								
SOURCE LEUKOCYTES	16																																																																																																																																																																																																																																								
SOURCE PLASMA	17																																																																																																																																																																																																																																								
RECOVERED PLASMA	18																																																																																																																																																																																																																																								
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19																																																																																																																																																																																																																																								
BLOOD BANK REAGENTS	20																																																																																																																																																																																																																																								
OTHER	21																																																																																																																																																																																																																																								
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) South Bend Medical Foundation, Inc. ATTN: Christine S. Saitz BS, MLT (ASCP) 530 N. Lafayette Boulevard South Bend, IN 46601-1098																																																																																																																																																																																																																																									
7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)																																																																																																																																																																																																																																									
7.1 E-MAIL ADDRESS 7.2 PHONE																																																																																																																																																																																																																																									
8. REPORTING OFFICIAL'S SIGNATURE  8.1 TYPED NAME Christine S. Saitz BS, MLT (ASCP) 8.2 E-MAIL ADDRESS csaitz@sbfm.org 8.3 PHONE 574-234-4176 x4522 8.4 DATE																																																																																																																																																																																																																																									