

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 3011776397
CFN:
2. U.S. LICENSE NUMBER
688

3. REASON FOR SUBMISSION
1. ☒ ANNUAL REGISTRATION
2. ☐ INITIAL REGISTRATION
3. ☐ CHANGE IN INFORMATION



FOR FDA USE ONLY 1

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.

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)

Medic, Inc.
Medic, Inc. (Crossville Center)
79 South Main Street
Crossville, TN 38555

4.1 PHONE 865-524-3074

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.)

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

Medic, Inc.
ATTN: Martha S. Cox, Chief Quality Officer
1601 Ailor Avenue
Knoxville, TN 37921

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

Martha S. Cox

8.1 TYPED NAME Martha S. Cox, Chief Quality Officer
8.2 E-MAIL ADDRESS mcox@medicblood.org
8.3 PHONE 865-524-3074 x688 8.4 DATE 1/19/2017

This form is authorized by Sections 510(b), (i) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (i) 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)).

9. TYPE OF OWNERSHIP

1. ☐ SINGLE PROPRIETORSHIP
2. ☐ PARTNERSHIP
3. ☒ CORPORATION profit non-profit
4. ☐ COOPERATIVE ASSOCIATION
5. ☐ FEDERAL (non-military)
6. ☐ U.S. MILITARY
7. ☐ STATE
8. ☐ COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
9. ☐ OTHER (Specify):

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)

1. ☐ COMMUNITY (NON-HOSPITAL) BLOOD BANK
2. ☐ HOSPITAL BLOOD BANK
3. ☐ PLASMAPHERESIS CENTER
4. ☐ PRODUCT TESTING LABORATORY
a. ☐ INDEPENDENT
b. ☐ ASSOCIATED w/ COMMUNITY or HOSPITAL BLOOD BANK
5. ☐ HOSPITAL TRANSFUSION SERVICE
a. ☐ APPROVED FOR MEDICARE REIMBURSEMENT
b. ☐ NOT APPROVED FOR MEDICARE REIMBURSEMENT
6. ☐ COMPONENT PREPARATION FACILITY
7. ☒ COLLECTION FACILITY
8. ☐ DISTRIBUTION CENTER
9. ☐ BROKERWAREHOUSE
10. ☐ OTHER (Specify):

U.S. LICENSE NUMBER OF PARENT FIRM 688

| 11. PRODUCTS | ALLOGENEIC | AUTOLOGOUS | DIRECTED | COLLECT | MANUAL APHERESIS | AUTOMATED APHERESIS | PREPARE | LEUKOCYTES REDUCED | IRRADIATED | DONOR REJECTED | TEST | STORE and DISTRIBUTE to OTHERS |
|-----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|---------|-------------------------------------|-------------------------------------|---------|-------------------------------------|------------|----------------|------|--------------------------------|
| WHOLE BLOOD | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | 1 | <input checked="" type="checkbox"/> | | | | | | | |
| RED BLOOD CELLS (RBC) | | | | 2 | | | | | | | | |
| RBC FROZEN | | | | 3 | | | | | | | | |
| RBC DEGLYCEROLIZED | | | | 4 | | | | | | | | |
| RBC REUVENATED | | | | 5 | | | | | | | | |
| RBC REUVENATED FROZEN | | | | 6 | | | | | | | | |
| RBC REUVENATED DEGLYCEROLIZED | | | | 7 | | | | | | | | |
| CRYOPRECIPITATED AHF | | | | 8 | | | | | | | | |
| PLATELETS | | | | 9 | | <input checked="" type="checkbox"/> | | | | | | |
| LEUKOCYTES/GRANULOCYTES | | | | 10 | | | | <input checked="" type="checkbox"/> | | | | |
| PLASMA | | | | 11 | | | | | | | | |
| PLASMA CRYOPRECIPITATE REDUCED | | | | 12 | | | | | | | | |
| FRESH FROZEN PLASMA | | | | 13 | | | | | | | | |
| 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 | | | | | | | | |