

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING1. REGISTRATION NUMBER
FEI: 1077605
CFN: 1077605
2. U.S. LICENSE NUMBER
6883. REASON FOR SUBMISSION
1. ☒ ANNUAL REGISTRATION
2. ☐ INITIAL REGISTRATION
3. ☐ CHANGE IN INFORMATIONFOR 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.
1601 Ailor Avenue
Knoxville, TN 37921-6702

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.)

MEDIC, Inc.
Medic Regional Blood Center

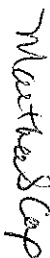
6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)

Medic, Inc.
ATTN: Martha S. Cox, Chief Quality Officer
1601 Ailor Avenue
Knoxville, TN 37921-6702

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 Martha S. Cox, Chief Quality Officer
8.2 E-MAIL ADDRESS mcox@medicblood.org
8.3 PHONE 865-524-3074 X668
8.4 DATE 01-08-2018

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)).

DISTRICT OFFICE: New Orleans
VALIDATED BY FDA: 20-DEC-2017
PRINTED BY FDA: 08-JAN-2018

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. ☐ BROKERS/WAREHOUSE
10. ☐ OTHER (Specify):

688
U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS			COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTED to OTHERS
<input checked="" type="checkbox"/> ALLOGENIC	<input checked="" type="checkbox"/> AUTOLOGOUS	<input checked="" type="checkbox"/> DIRECTED	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
WHOLE BLOOD			<input checked="" type="checkbox"/>								
RED BLOOD CELLS (RBC)					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
RBC FROZEN						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
RBC DEGLYCEROLIZED						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
RBC RELIQUENATED											
RBC RELIQUENATED FROZEN											
RBC RELIQUENATED DEGLYCEROLIZED											
CRYOPRECIPITATED AHF						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
PLATELETS					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
LEUKOCYTES/GRANULOCYTES											
PLASMA						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
PLASMA CRYOPRECIPITATE REDUCED						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
FRESH FROZEN PLASMA					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
LIQUID PLASMA						<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
THERAPEUTIC EXCHANGE PLASMA											
SOURCE LEUKOCYTES											
SOURCE PLASMA											
RECOVERED PLASMA						<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
BLOOD PRODUCTS FOR DIAGNOSTIC USE											
BLOOD BANK REAGENTS											
OTHER Cryoprecipitated AHF Pooled Platelet Pheresis (automated)			<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>