DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER	3. REASON FOR SUBMISSION	FOR FDA USE ONLY
FEI: 3011776397	.1 ☑ ANNUAL REGISTRATION	
CFN:	.2 ☐ INITIAL REGISTRATION	
2. U.S. LICENSE NUMBER	.3 ☐ CHANGE IN INFORMATION	DISTRICT OFFICE: New Orleans
688		VALIDATED BY FDA: 20-DEC-2017
		PRINTED BY FDA: 08-JAN-2018

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 33.3(a)).

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, county, 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.)

MEDIC, Inc. (Crossville)

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include number and street, city, state, county, 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 NAME

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 1-8-2018

FORM FDA 2830 (05/2015)   PREVIOUS EDITION IS OBSOLETE

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
.5 ☐ HOSPITAL TRANSFUSION SERVICE
   a. ___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
   ___ APPROVED FOR MEDICARE REIMBURSEMENT
   ___ NOT APPROVED FOR MEDICARE REIMBURSEMENT
.6 ☐ COMPONENT PREPARATION FACILITY
.7 ☑ COLLECTION FACILITY ⎫
.8 ☐ DISTRIBUTION CENTER ⎬ 688
.9 ☐ BROKER/WAREHOUSE ⎭ U.S. LICENSE NUMBER OF PARENT FIRM
.10 ☐ OTHER (Specify):

11. PRODUCTS

		COLLECT						
ALLOGENEIC ☒ AUTOLOGOUS ☒ DIRECTED ☒		(.1)	MANUAL APHERESIS (.2)	AUTOMATED APHERESIS (.3)	PREPARE (.4)	LEUKOCYTES REDUCED (.5)	IRRADIATED (.6)	DONOR RETESTED (.7)	TEST (.8)	STORE and DISTRIBUTE to OTHERS (.9)
WHOLE BLOOD	1	X						
RED BLOOD CELLS (RBC)	2							
RBC FROZEN	3							
RBC DEGLYCEROLIZED	4							
RBC REJUVENATED	5							
RBC REJUVENATED FROZEN	6							
RBC REJUVENATED DEGLYCEROLIZED	7							
CRYOPRECIPITATED AHF	8							
PLATELETS	9		X		X			
LEUKOCYTES/GRANULOCYTES	10							
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							