DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

Ext.:

FEI: 3015976668

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2023
Last Registration Receipt Date: 11/29/2022
Summary Report Print Date: 12/01/2022

Legal Name and Location:

Eurofins Donor & Product Testing, Inc. Winston Salem

1430 Westbrook Plaza Dr

Suite B

Winston-Salem, North Carolina 27103

USA

FEI:

Phone: 336-666-5101

Reporting Official:

Craig P Thomsen, Director of RA/QA

6933 South Revere Parkway Centennial, Colorado 80112

LICA

Phone: 855-875-5227 Ext. 810

RegulatoryAffairs@eurofins-vrl.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

No

	Donor Type(s)	Establishment Functions										
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane				Х								
Blood Vessel				X								
Bone				X								
Cardiac Tissue - non-valved				X								
Cartilage				X								
Cornea				X								
Dura Mater				X								
Embryo	Anonymous, Directed, SIP			X								
Fascia				X								
Heart Valve				Х								
HPC Apheresis	Autologous, Family Related			Х								
HPC Cord Blood	Autologous, Family Related			Х								
Ligament				Х								
Nerve Tissue				Х								
Oocyte	Anonymous, Directed, SIP			Х								
Ovarian Tissue				Х								
Pancreatic Islet Cells - autologous				Х								
Parathyroid				Х								
Pericardium				Х								
Peripheral Blood Mononuclear Cells	Autologous, Family Related			Х								
Peritoneal Membrane				Х								
Sclera				Х								
Semen	Anonymous, Directed, SIP			Х								
Skin				Х								
Tendon				Х								
Testicular Tissue				Х								
Tooth Pulp				Х								
Umbilical Cord Tissue				Х								

Legal Name:

Additional Information:	No additional information provided.
Additional information.	ino additional inionnation provided

Proprietary Name(s):

FEI: 3015976668 Legal Name: Eurofins Donor & Product Testing, Inc. Winston Salem