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# HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query Establishment Details

#### Establishment Name and Location

Current Status: Registered

Last Annual Registration Year: 2024

FDA Establishment Identifier (FEI): 3013239405

Establishment Name: BioStem Life Sciences
Address: 2836 Center Port Circle

City: Pompano Beach

State: Florida Zip: 33064

Country: UNITED STATES

Phone: 954-380-8342

#### **Establishment Functions**

| Types of HCT/Ps                     | Recover | Screen | <b>Donor Testing</b> | Package | Process    | Store      | Label      | Distribute |
|-------------------------------------|---------|--------|----------------------|---------|------------|------------|------------|------------|
| Amniotic Membrane                   |         |        |                      | ₩í      | <b>√</b> í | <b>₩</b> ĺ | <b>₩</b> ĺ | ₩í         |
| Blood Vessel                        |         |        |                      |         |            |            |            |            |
| Bone                                |         |        |                      |         |            |            |            |            |
| Cardiac Tissue - non-valved         |         |        |                      |         |            |            |            |            |
| Cartilage                           |         |        |                      |         |            |            |            |            |
| Cornea                              |         |        |                      |         |            |            |            |            |
| Dura Mater                          |         |        |                      |         |            |            |            |            |
| Embryo                              |         |        |                      |         |            |            |            |            |
| Fascia                              |         |        |                      |         |            |            |            |            |
| Heart Valve                         |         |        |                      |         |            |            |            |            |
| HPC Apheresis                       |         |        |                      |         |            |            |            |            |
| HPC Cord Blood                      |         |        |                      |         |            |            |            |            |
| Ligament                            |         |        |                      |         |            |            |            |            |
| Nerve Tissue                        |         |        |                      |         |            |            |            |            |
| Oocyte                              |         |        |                      |         |            |            |            |            |
| Ovarian Tissue                      |         |        |                      |         |            |            |            |            |
| Pancreatic Islet Cells - autologous |         |        |                      |         |            |            |            |            |
| Parathyroid                         |         |        |                      |         |            |            |            |            |
| Pericardium                         |         |        |                      |         |            |            |            |            |
| Peripheral Blood Mononuclear Cells  |         |        |                      |         |            |            |            |            |
| Peritoneal Membrane                 |         |        |                      |         |            |            |            |            |
| Sclera                              |         |        |                      |         |            |            |            |            |
| Semen                               |         |        |                      |         |            |            |            |            |
| Skin                                |         |        |                      |         |            |            |            |            |
| Tendon                              |         |        |                      |         |            |            |            |            |

| Testicular Tissue     |  |  |  |  |
|-----------------------|--|--|--|--|
| Tooth Pulp            |  |  |  |  |
| Umbilical Cord Tissue |  |  |  |  |

## Establishment HCT/P Listing

| Types of HCT/Ps                       | HCT/Ps<br>Described<br>in 21 CFR<br>1271.10 | Proprietary Names   |
|---------------------------------------|---|---|
| Amniotic Membrane                     | X   | Vendaje, Vendaje AC, Vendaje Optic, AmnioWrap2,<br>Avenova, American Amnion, American Amnion AC,<br>American Amnion Tri-Layer |
| Blood Vessel                          |   |   |
| Bone                                  |   |   |
| Cardiac Tissue - non-valved           |   |   |
| Cartilage                             |   |   |
| Cornea                                |   |   |
| Dura Mater                            |   |   |
| Embryo                                |   |   |
| Fascia                                |   |   |
| Heart Valve                           |   |   |
| HPC Apheresis                         |   |   |
| HPC Cord Blood                        |   |   |
| Ligament                              |   |   |
| Nerve Tissue                          |   |   |
| Oocyte                                |   |   |
| Ovarian Tissue                        |   |   |
| Pancreatic Islet Cells - autologous   |   |   |
| Parathyroid                           |   |   |
| Pericardium                           |   |   |
| Peripheral Blood Mononuclear<br>Cells |   |   |
| Peritoneal Membrane                   |   |   |
| Sclera                                |   |   |
| Semen                                 |   |   |
| Skin                                  |   |   |
| Tendon                                |   |   |
| Testicular Tissue                     |   |   |
| Tooth Pulp                            |   |   |
| Umbilical Cord Tissue                 |   |   |

## HCT/P Listing - Donor Information

| Types of HCT/Ps                    | SIP | Directed | Anonymous | Autologous | Family Related |
|------------------------------------|-----|----------|-----------|------------|----------------|
| Embryo                             |     |          |           |            |                |
| HPC Apheresis                      |     |          |           |            |                |
| HPC Cord Blood                     |     |          |           |            |                |
| Oocyte                             |     |          |           |            |                |
| Peripheral Blood Mononuclear Cells |     |          |           |            |                |
| Semen                              |     |          |           |            |                |

**Print Date: 03/01/2024** 

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