

**ANNEX 1 FORM TO LIST CLASS 1 CELL, TISSUE OR GENE THERAPY PRODUCTS**

**Product Notification No. CTGT0054N**

| S/N | Product Owner     | Product Name                                                                              | Product Code | Name & Address of Manufacturing Site                                  | Country of Manufacturer | Notification Number<br>( <i>applicable for notified products</i> ) |
|-----|-------------------|-------------------------------------------------------------------------------------------|--------------|-----------------------------------------------------------------------|-------------------------|--------------------------------------------------------------------|
| 1   | ISP Surgical, LLC | AmnioTek® Processed Amniotic Membrane Allograft Transplant for the Ocular Surface         | BC-AT        | Biocover Laboratories -<br>716-L, Model Town, Karnal<br>132001, INDIA | India                   |                                                                    |
| 2   | ISP Surgical, LLC | AmnioTek®-2 Processed Amniotic Membrane Allograft Transplant for the Ocular Surface       | BC-AT2       | Biocover Laboratories -<br>716-L, Model Town, Karnal<br>132001, INDIA | India                   |                                                                    |
| 3   | ISP Surgical, LLC | AmnioTek®-C Processed Amniotic Membrane Allograft Transplant for the Ocular Surface       | BC-ATC       | Biocover Laboratories -<br>716-L, Model Town, Karnal<br>132001, INDIA | India                   |                                                                    |
| 4   | ISP Surgical, LLC | AmnioTek®-C (Kit) Processed Amniotic Membrane Allograft Transplant for the Ocular Surface | BC-ATC       | Biocover Laboratories -<br>716-L, Model Town, Karnal<br>132001, INDIA | India                   |                                                                    |
| 5   | ISP Surgical, LLC | AmnioTek®-Vision Processed Amniotic Membrane Allograft Transplant for the Ocular Surface  | BC-ATV       | Biocover Laboratories -<br>716-L, Model Town, Karnal<br>132001, INDIA | India                   |                                                                    |
| 6   | ISP Surgical, LLC | AmnioTek®-G Processed Amniotic Membrane Allograft Transplant for the Ocular Surface       | BC-ATG       | Biocover Laboratories -<br>716-L, Model Town, Karnal<br>132001, INDIA | India                   |                                                                    |