## **Risk Assessment Record**

| No. | Process       | Hazard   | Rescondity<br>forwardite<br>sequence or<br>continuation of<br>doorts   | Name  | Severity | Probability | Risk<br>acceptability | Acceptable<br>risk<br>(Yes/No) | Rob control<br>options and<br>rottonals       | Mak control<br>measures   |
|-----|---------------|--|--|---|----------|-------------|-----------------------|--------------------------------|---|---|
| 1   | Purchasing    | Non-<br>biocompatible<br>raw material            | Planson flos<br>proferoid residence<br>disable to east<br>flosocomposition,<br>prof done not<br>floore all<br>leavencery<br>parts (Scotter | Donce or othergon<br>becaution of the<br>pattern                              | 3        | 2           | 6                     | No                             | Process control /<br>education of<br>sectors  | the appropriet man<br>for appropriet of<br>transfer man<br>provide<br>forces or<br>the control of<br>the control of<br>the control of<br>the control of<br>the<br>transfer of<br>the<br>transfer of<br>the<br>transfer of<br>transfer |
| 2   | Sterilization | Non-sterile<br>device                            | Distribution  repripated & self properly  materials and published  | inglection of the<br>pottern  | 3        | 2           | 6                     | No                             | Process control /<br>education of<br>scorture | A chardination<br>beachine mad be<br>established and<br>tepsions<br>beaconsined   |
| 3   | Storage       | Storing the product at an inadequate temperature |  | Cook or otherpo<br>seaction of the<br>potient due to<br>the decise<br>(hamps) | 3        | 2           | 6                     | No                             | Process control /<br>education of<br>sectors  | No Processorantees<br>Insuel Sal<br>Salfbrested   |
| 4   |               |  |  |   |          |             |                       |                                |   |   |

| Risk control<br>serfication   | Chapter) | Severity | Probability | Residual<br>Roik<br>acceptability | Security<br>magnificate | Benefit<br>frequency | Benefit<br>value | Servette - risk<br>ratio | Security<br>explanation   |
|---|----------|----------|-------------|-----------------------------------|-------------------------|----------------------|------------------|--------------------------|---|
| COT of Representations Inspections, alone, alone, fractions; fractions; fractions fractions fractions; alone, fractions |          | 33       | 1           |                                   |                         | ന                    | 9                |                          | Stock Service is<br>Stocker Stee Stee<br>Sigher Stee Stee<br>set of country<br>Stee othersis or<br>Soot reaction.       |
| Clare State State of<br>Security, Abrille /<br>Clare State State<br>and State State or registers,<br>disting  |          | 2        | 1           |                                   |                         | ίω                   | 9                |                          |   |
| Continuence and<br>Continuence<br>Second, services,<br>Service / Continuence<br>service and<br>Services,<br>Services,   |          | 3        | 1           |                                   |                         | 3                    | 9                |                          | Strong Dring saming<br>devices to brighter<br>Otion Otion road<br>counted by otherspel<br>of saming<br>beregion others. |