Form Details Page 1 of 4

|  |  | Released by \$22              | on 17/11/2016 14:13:04 Pr           |
|--|--|-------------------------------|-------------------------------------|
| eport Informat on Sect on  | Parada Managara #                                  | Danastada Dafarrasa #1        | P+ T                                |
| eport #:   | Records Management #:                              | Reporter's Reference #:       | Report Type:                        |
| 2764<br>port Status:   | Sponsor's Reported Category:                       | WIR01  Date of Adverse Event: | Date of Initial Report:             |
|  | Sponsor's Reported Category.                       | Date of Adverse Event.        | - Proceedings                       |
| riage<br>ate of Final Report:  | Date of In tial TGA Action:                        | Reviewed by DIRE:             | 27/07/2018  Date Response Received: |
| 7/07/2018  | 27/07/2018   | Neviewed by DINE.             | Date Response Received.             |
| ate Completed:   | Operator at Time of Event:                         | If 'Other' Operator Selected: | Reporter Conf dentiality:           |
| ource of Report:   | If 'Other' Source Selected:                        | Type of Initial Act on:       | No                                  |
| ent Descript on for Website Publ   | lication:  |                               |                                     |
| 22   |  |                               |                                     |
| inical Event Information:  |  |                               |                                     |
| 22   |  |                               |                                     |
| umber of Incidents in Report:  | Contacts   | Alternative Person Title:     | Alternative Person First Name:      |
|  | Contact:   | Alternative Person Title:     | Alternative Person FIRST Name:      |
| Itarnativa Barcan Surnama  | Reporter   | Alternative Person Farm       |                                     |
| ternative Person Surname:  | Alternative Person Phone:                          | Alternative Person Fax:       |                                     |
| tient Information  |  | - <del></del>                 |                                     |
| 2  | Weight:  | S22                           | 4                                   |
| atient Focused Corrective Action   | J. L.  |                               |                                     |
| 22   |  |                               |                                     |
| PROGRAM TO POST OF THE POST OF THE PROGRAM TO SECOND   |  | •                             |                                     |
| ther Dev ces Involved:   |  | •                             |                                     |
| other Dev ces Involved:  |  | •                             |                                     |
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| ther Dev ces Involved:   |  |                               |                                     |
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| ther Dev ces Involved:  bm tting Reporter Section  |  |                               | Initial Reporter Confidential       |
| tial Reporter Section  tial Reporter Section  Above?:  | If No, fill out the following:                     |                               | Initial Reporter Conf dential:      |
| tial Reporter Section  Sabove?:  |  |                               | Initial Reporter Conf dential:      |
| tial Reporter Section  Sabove?:  es earch Reporter By Surname:   | If No, fill out the following:                     |                               | Initial Reporter Conf dential:      |
| mer Dev ces Involved:  mutting Reporter Section  ial Reporter Sect on Above?:  assarch Reporter By Surname:  | If No, fill out the following: In tial Reporter #: |                               | Initial Reporter Conf dential:      |
| other Dev ces Involved:  Jubin thing Reporter Section  22  Jubin thing Reporter Section  22  Jubin thing Reporter Section  23  Jubin thing Reporter Section  24  Jubin thing Reporter Section  25  Jubin thing Reporter Section  26  Jubin thing Reporter Section  27  Jubin thing Reporter Section  28  Jubin thing Reporter Section  29  Jubin thing Reporter Section  20  Jubin thing Reporter Section  20  Jubin thing Reporter Section  20  Jubin thing Reporter Section  21  Jubin thing Reporter Section  22  Jubin thing Reporter Section  22  Jubin thing Reporter Section  23  Jubin thing Reporter Section  24  Jubin thing Reporter Section  25  Jubin thing Reporter Section  26  Jubin thing Reporter Section  27  Jubin thing Reporter Section  28  Jubin thing Reporter Section  29  Jubin thing Reporter Section  20  Jubin thing Rep | If No, fill out the following: In tial Reporter #: | Surname:                      | Initial Reporter Conf dential:      |

Form Details Page 2 of 4

| Postcode:                                   | code: Phone: |   |              | Fax:                 | Fax:                    |                   | Mobile:                   |  |  |
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| mail:                                       |              |   |              |                      |                         |                   |                           |  |  |
| vica Information Cost a                     |              |   |              |                      |                         |                   |                           |  |  |
| evice Informat on Sect o<br>roduct Exempt:  | П            | T( ) ( ) ( ) ( )                        |              | Search Device        | ce ARTG:                | Dev               | ce ARTG #:                |  |  |
|   |              | If No, fill out ART                     | IG No:       |                      |                         |                   |                           |  |  |
| Therapeut c L cence Type: Product Licence C |              |   | Category:    | Device Class         | :                       | GMDN / UMDN Code: |                           |  |  |
| MDN / UMDN Text:                            |              |   | Brand Name   | Brand Name:          |                         |                   |                           |  |  |
|   |              |   |              | s22                  |                         |                   |                           |  |  |
| nitial Device Descript on                   | :            |   |              | 100                  |                         |                   |                           |  |  |
| Distal protection filter                    |              |   |              |                      |                         |                   |                           |  |  |
| sage of Device:                             |              | Software Versio                         | n:           |                      |                         |                   |                           |  |  |
| lodel #:                                    |              | Serial #:                               |              | Batch #:             |                         | Lot               | #:                        |  |  |
|   |              | p290705s                                |              |                      |                         | DS                | 17003                     |  |  |
| urchase Date:                               |              | Expiry Date:                            |              | Date of Impl         | ant:                    | -11               | e of Explant:             |  |  |
| 26/07/2018                                  |              | 12/12/2019                              |              | 26/07/2018           |                         |                   | /07/2018                  |  |  |
| 22  | •            | 12,12,2019                              |              | 20/07/2010           |                         |                   |                           |  |  |
|   | 7            |   |              |                      |                         |                   |                           |  |  |
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|   |              |   |              |                      |                         |                   |                           |  |  |
|   |              |   |              |                      |                         |                   |                           |  |  |
| nufacturer Information                      | Section      |   |              |                      |                         |                   |                           |  |  |
| anufacturer Name:                           |              |   |              | Manufacture          | r Client Id:            | Add               | ress 1:                   |  |  |
| 22  |              | 200 00000000000000000000000000000000000 |              |                      |                         | s22               | 100 07                    |  |  |
| ddress 2:                                   |              | Town/Suburb:                            |              | State/Provin         | ce:                     | Country 5         |                           |  |  |
| Na Food of Publish                          |              |   |              | 1 Journey            |                         | Isr               | Israel                    |  |  |
| ostcode:                                    |              | Phone:                                  |              | Fax:                 |                         |                   |                           |  |  |
| 522   |              | s22                                     |              |                      |                         | ]                 |                           |  |  |
| mail:                                       |              |   |              | Manufacture          | r Informed:             | Dat               | e Aware of Adverse Event: |  |  |
| ontact T tle:                               |              | Contact First Na                        | me:          | Contact Surname:     |                         |                   |                           |  |  |
|   |              |   |              |                      |                         |                   |                           |  |  |
| upplier Information Sect                    | ion          |   |              |                      |                         |                   |                           |  |  |
| upplier Name:                               |              |   |              | Address 1:           |                         | Add               | ress 2:                   |  |  |
| 22  |              |   |              | s22                  |                         |                   |                           |  |  |
| own/Suburb:                                 |              | State:                                  | State:       |                      | Postcode:               |                   | Phone:                    |  |  |
| 22  |              | NSW                                     |              | 2065                 | 2065                    |                   | s22                       |  |  |
| ax:   |              | Email:                                  |              |                      |                         | Sup               | Supplier Informed:        |  |  |
|   |              | info@diversede                          | vices.com.au | ı                    |                         | Yes               | fes                       |  |  |
| ate of Supplier Contact                     |              | Contact Title:                          |              | Contact First        | Name:                   | Con               | tact Surname:             |  |  |
| 26/07/2018                                  |              | s22                                     |              | s22                  |                         | s2:               | 2                         |  |  |
| ontact Phone: Contact Fax:                  |              |   | 143 <u></u>  |                      | 36                      | <u> </u>          |                           |  |  |
| 22  |              |   |              |                      |                         |                   |                           |  |  |
| atist cs Checklist Sect o                   |              |   |              |                      |                         |                   |                           |  |  |
|   |              | d n                                     | The second   |                      | nud.t.a.t.              | 1220              | First Decision Rose See   |  |  |
| ate:  | Asse         | ssed By:                                | FOR          | webs te publicat on: | Ready for Publicat o    | on:               | Exclude report from DIRE  |  |  |
| 27/07/2018                                  |              |   |              | 57 <b>4-16</b> 57    | No                      |                   | 21.17.18                  |  |  |
| ample Received:                             |              |   |              | sable:               | Single Use:             |                   | Potential Effect:         |  |  |
| ctual Effect:                               | Yes          | Yes Nonjured Party:                     |              |                      | Yes Found Pr or To Use: |                   | Risk Frequency:           |  |  |
| ccai Liidh.                                 | Injul        | ca raity.                               |              |                      | Todad From 10 USE       | •                 | mak riequency.            |  |  |
| isk Sever ty:                               | Risk         | Detectability:                          | Class        | sification:          | Investigated:           |                   | Date of DIRE Meeting:     |  |  |
| IDE Marking M                               |              |   |              |                      |                         |                   |                           |  |  |
| IRE Meeting Notes:                          |              |   |              |                      |                         |                   |                           |  |  |
|   |              |   |              |                      |                         |                   |                           |  |  |

Form Details Page 3 of 4

| Search Sponso  | 13.  |  | Name:  |  |   | Client #:  |            |           |                        |                 |
|--|--|--|--|--|---|--|------------|-----------|------------------------|-----------------|
| Attent on To:  |  |  | Address 1:   |  | Addr  | ess 2:   |            | Tov       | vn/Suburb:             |                 |
| State:   |  |  | Postcode:  |  | Phon  | e:   |            | Fax       | •                      |                 |
| Email:   |  |  |  |  |   |  |            |           |                        |                 |
| :maii.   |  |  |  |  |   |  |            |           |                        |                 |
|  | format on Sec  | t on   |  |  |   |  |            |           |                        |                 |
| Dev ce Analysis  | s Results:   |  |  |  |   |  |            |           |                        |                 |
| Corrective/Prev  | ventative Actio  | ons:   |  |  |   |  |            |           |                        |                 |
| Details of Simil   | lar Events:  |  |  |  | Addit   | ional Details (use t   | or tables  | s):       |                        |                 |
|  |  |  |  |  |   | A  |            |           |                        |                 |
| Number of Sim  | ilar Events:   |  |  |  | Rate  | of Similar Events:   |            |           |                        |                 |
| Countries Simil  | lar Events Also  | Occurred:  |  |  |   |  |            |           |                        |                 |
|  |  |  |  |  |   |  |            |           |                        |                 |
| Add t onal Com   | ments:   |  |  |  |   |  |            |           |                        |                 |
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Form Details Page 4 of 4

| Cause Deta | ails                       |                |              |              |            |                   |     |             |          |        |
|------------|----------------------------|----------------|--------------|--------------|------------|-------------------|-----|-------------|----------|--------|
| Cause of P | roblem (Level 1)           | Cause o        | f Problem (L | evel 2)      | If 'Othe   | r' Cause Selected |     |             |          |        |
| Outcome D  |                            |                |              |              |            |                   |     |             |          |        |
| Outcome o  | of Investigat on           |                | If Ad        | dd t onal Ou | itcome Det | tail Requested    |     |             |          |        |
| Recall Nur |                            |                |              |              |            |                   |     |             |          |        |
| Investigat | t on Summary:              |                |              |              |            |                   |     |             |          |        |
| Flow Deta  | ils DIR-REQ - D<br>Details | evice Incident | Request 1    | 45098        |            |                   |     |             |          |        |
| ID         | Туре                       | Location       | Status       | Assigne      | d By       | Assigned To       |     | Assigned On | Prior ty | Attach |
| 145098     | DIR-REQ                    |                | Triage       | theta        |            | IRIS Coordina     | cor | 27/07/2018  | Normal   | 0      |
|            |                            |                |              |              |            |                   |     |             |          |        |
| Signature  | Details                    |                |              |              |            |                   |     |             |          |        |
| Role       | IRIS Invest                | igator         |              |              |            |                   |     |             |          |        |
| User       |                            |                |              |              |            |                   |     |             |          |        |
| Signed At  |                            |                |              |              |            |                   |     |             |          |        |
| Comment    |                            |                |              |              |            |                   |     |             |          |        |