



**The Reference Countries:**

The below list of countries whose competent NRA (national Regulatory Authority) are designated as SRA (stringent regulatory Authority) as per the current interim definition of SRA, your product should meet the following criteria: In addition to having registration and marketing approval of the product in the country of origin, it has:

**A. To be registered with the competent National Regulatory Authority in at least one of these countries:**

- |                                       |                                       |
|---------------------------------------|---------------------------------------|
| 1. Australia                          | 12. Italy                             |
| 2. Austria                            | 13. Japan                             |
| 3. Belgium                            | 14. Netherlands                       |
| 4. Canada                             | 15. Portugal                          |
| 5. Denmark                            | 16. Spain                             |
| 6. Finland                            | 17. Sweden                            |
| 7. France                             | 18. Switzerland [SwissMedic],         |
| 8. Germany                            | 19. United Kingdom [MHRA],            |
| 9. Iceland                            | 20. United States of America [US FDA] |
| 10. Ireland                           | 21. Norway                            |
| 11. GCC Central registration (GCC DR) |                                       |

**B. To be registered with the competent National Regulatory Authority in at least four of these countries:**

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|-------------------|------------------|
| 1. Bulgaria       | 9. Liechtenstein |
| 2. Croatia        | 10. Lithuania    |
| 3. Cyprus         | 11. Luxembourg   |
| 4. Czech Republic | 12. Malta        |
| 5. Estonia        | 13. Poland       |
| 6. Greece         | 14. Romania      |
| 7. Hungary        | 15. Slovakia     |
| 8. Latvia         | 16. Slovenia     |