



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

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

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