



- #1 : Dehydrated Culture media are no public health risk or low personal risk and therefore are not covered under Annexure I
- #2: The devices used for self-testing are intended by the manufacturer to be used by laypersons in a home environment. Dehydrated Culture Media has to be used at professional workplaces and by experts.
- #3: As per European Directive 98/78/EC on In-vitro Diagnostic Devices, the material can be grouped under “All other In-vitro Diagnostic Devices other than those covered by Annex II and IVDs for self-testing”; and hence have selected to proceed for EC Declaration of Conformity Document.