

# CHECKLIST

**Form Name:** Risk Classification

**Category:** IVD

## Checklist for Risk Classification of In-vitro Diagnostic Medical device

Section no.	Checklist Name	Is Mandatory
1.0	Application	Yes
2.0	Product Details	Yes
2.1	Technical device details including Intended use, Indication, Device principle, technology, composition/components/accessories etc.	Yes
2.2	Catalogue of products/IFU/User manual/Package insert	Yes
2.3	Product Labels/product design	Yes
2.4	Regulatory status of the proposed device/similar device registered in other countries viz. USA, UK, EU, Australia, Canada or Japan etc.	Yes
2.5	Any other information, if available	No