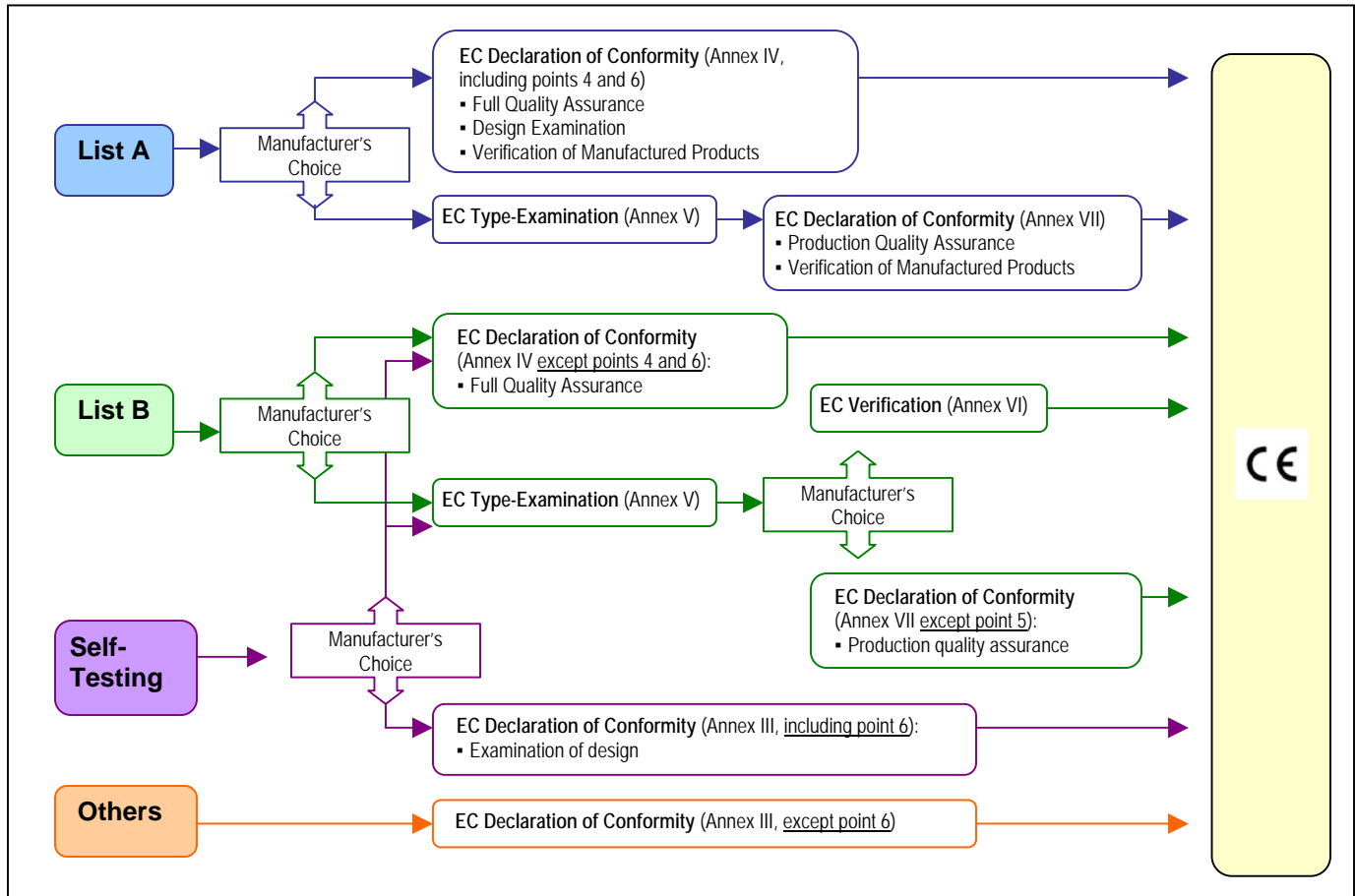


The below chart was developed by LNE/G-MED's technical team to clearly demonstrate IVD assessment routes. LNE has been helping IVD manufacturers secure CE Marking for over a decade – ever since the IVD Directive first came into effect.

If you have questions about IVD assessment routes, CE Marking or other medical device issues, contact G-MED North America's IVD Project Manager **Darren Walsh** at: darren.walsh@lne-gmed.com or (301) 495-0477.

Assessment Routes for In Vitro Diagnostic (IVD) Devices under Directive 98/79/EC



Under the In Vitro Diagnostic Directive (IVDD), medical devices are categorized based on whether they are specifically listed in Annex II of the directive (list A for the most risky devices, list B for lower risk devices) and whether they are intended for self-testing.

Devices fall into one of the following categories:

- **List A:** blood transfusion or graft transplantation.
- **List B:** lower level of risk but still relate to the diagnostic of critical pathologies or state of health and must demonstrate reliability.
- **Self Testing:** have higher potential of misuse, misinterpretation of the test result or test failures with significant impact on the medical decision that the test result may lead to.
- **Other:** covers devices that don't fit into any of the above groups.