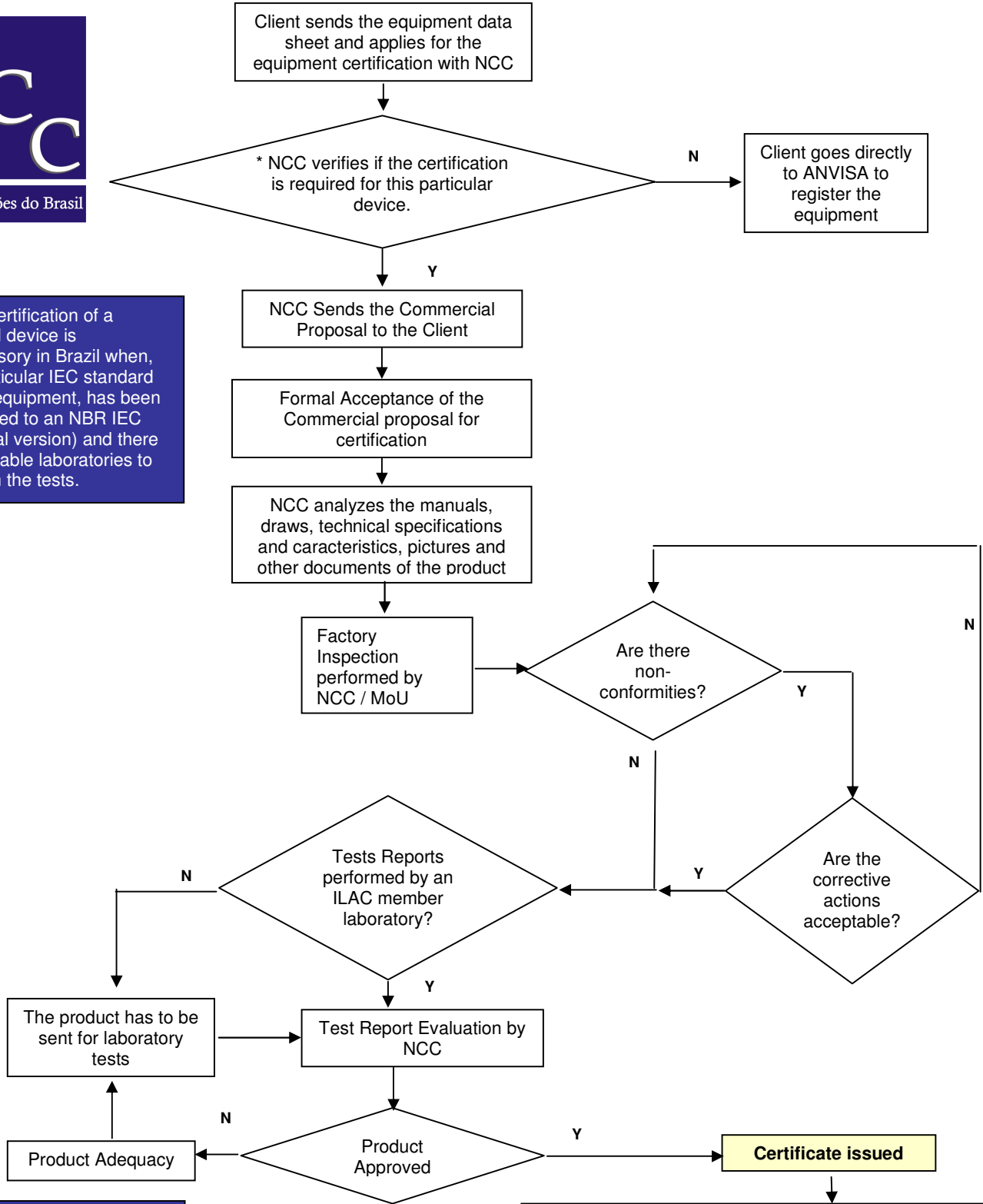


MEDICAL DEVICES
Certification Process in Brazil



* The certification of a medical device is compulsory in Brazil when, the particular IEC standard of this equipment, has been translated to an NBR IEC (national version) and there are capable laboratories to perform the tests.



Certificate maintenance
Factory inspection must be performed once a year for 5 years. During this time, further laboratory tests will only be required if the product changes.

The certificate shall be presented at Anvisa (National Health Agency), along with the documentation required on:
<http://www.anvisa.gov.br/produtosaude/reg/registro.htm>.