MEDICAL DEVICES
Certification Process in Brazil

Certificações do Brasil

Client sends the equipment data sheet and applies for the equipment certification with NCC

* NCC verifies if the certification is required for this particular device.

N → Client goes directly to ANVISA to register the equipment

Y

* 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.

NCC Sends the Commercial Proposal to the Client

Formal Acceptance of the Commercial proposal for certification

NCC analyzes the manuals, draws, technical specifications and caracteristics, pictures and other documents of the product

Factory Inspection performed by NCC / MoU

Are there non-conformities?

Y → Are the corrective actions acceptable?

N → Are the corrective actions acceptable?

Are the corrective actions acceptable? → Y → Tests Reports performed by an ILAC member laboratory?

Are the corrective actions acceptable? → N → (back to) Are there non-conformities?

Tests Reports performed by an ILAC member laboratory?

N → The product has to be sent for laboratory tests

Y → Test Report Evaluation by NCC

The product has to be sent for laboratory tests → Test Report Evaluation by NCC

Test Report Evaluation by NCC → Product Approved

Product Approved

N → Product Adequacy

Product Adequacy → The product has to be sent for laboratory tests

Y → **Certificate issued**

Certificate issued → 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.

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.

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