

# Medical Device Testing

Nemko has extensive experience testing many kinds of medical devices. Our testing laboratories feature advanced test equipment that can measure and stress your product to make sure it fulfills all compliance requirements for your planned markets. Our diverse and experienced team brings in-depth knowledge and understanding of various complex medical equipment technologies. The medical device market is expected to grow rapidly soon.

## How Nemko can help :

1. Provide [pre-compliance](#) [1] testing requirements during the design and development phase
2. Assist you with verification testing on qualified products as per requirement
3. Support you with reduction of time to market

## Through us you can access the following facilities:

1. Medical Device Directive, Class I-m (measuring), I-s (sterile), IIa, IIb, III
2. EC Declaration of Conformity; compiling of test reports and required documentation for the technical file
3. EC Type Examination Certificate
4. Full Quality Assurance with reference to EN ISO 13485
5. Production & Product Quality Assurance with reference to EN/ISO 13485
6. EC Verification

In India to implement the regulation on medical devices, the CDSCO published two amendments to the 2017 medical device regulation. Both the amendments came into force on 1st April 2020. For all Gazette notifications, [click here](#) [2].

For more information about how Nemko can help your organization with medical device testing and certification [contact us](#) [3] or mail us at [india@nemko.com](mailto:india@nemko.com) [4] / [anshuman.dash@nemko.com](mailto:anshuman.dash@nemko.com) [5] or give us a call at +91-9205690574 .

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## Links

[1] <https://www.nemko.com/pre-compliance>

[2] <https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/>

[3] [https://share.hsforms.com/1hZbT0BVLSkaHI-yqC\\_MDzQ3iuwe](https://share.hsforms.com/1hZbT0BVLSkaHI-yqC_MDzQ3iuwe)

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[6] <https://www.nemko.com/india>

[7] <https://nabl-india.org/nabl/index.php?c=search&m=searchlabcertificate&cno=4591>

[8] <https://www.nemko.com/product-testing/safety-testing/testing-medical-equipment>

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