

TNV Certification Pvt Ltd

Quotation Questionnaire



TNV-CE-001

Company Information

Company Name

Address

Contact Person

Title

Tel

Fax

Mail

List of Products for Certification, Intended Use and Classifications

Products / Intended Use	Directive MDD / IVDD/ AIMD	Classification / Comments (e.g. applicable rule(s))

Notes: Please attach sales brochure or Instruction for Use for every each product list. Please attach a separate sheet for more products, if applicable.

What kind of certification are you seeking?

MDD (93/42/EEC) EC directive on Medical Devices	IVDD (98/79/EC) EC directive on In Vitro Diagnostics	AIMD (90/385/EEC) EC directive on Active Implantable Medical Devices	Quality Management System certificate
Annex II.3	Annex III.6	Annex 2	No certificate
Annex II.4 + II.3	Annex IV.3		EN ISO 9001:2000
Annex III + IV	Annex IV.3 + IV.4 + IV.6		EN 46003:1996
Annex III + V	Annex V + VI		Other, specify below
Annex III + VI	Annex V + VII		
Annex IV	Annex V + VII.3 + VII.5		
Annex V			
Annex VI			

Please enclose copies of already existing EC directive approvals

Do any QA system certificates already exist?

Do any QA system certificates already exist?

Yes

No

Please enclose copies of already existing QA system certificates

Information on Facilities and Number of Employees:

TNV Certification Pvt Ltd

Quotation Questionnaire



Name / Address of facility	Quality Control	Design & Dev.	Purchasing	Production	Warehouse	Sales, Service	Other	Total Employees	No. of Shifts

Please attach a separate sheet for more facilities, if applicable.

Other Information

Do you sell products under your own company name, which are produced by other companies?	Yes	No
If yes, did the original equipment manufacturer (OEM) already carry out a conformity assessment procedure?	Yes	No
<i>Please enclose copies of already existing EC directive certificates</i>		
What is your preferred schedule for assessment?		
What is your preferred schedule for assessment?		
Pre-Assessment by:		
Certification Assessment by:		

General Comments / Other Requirements:

Signature:	Date:
Fax to: +91 (522) 2759881	Mail to: info@isoindia.org

We also dealt in ISO 9001:2008, ISO 14001:2004, OHSAS 18001:2007 & ISO 22000:2005, ISO 27001:2007 Certification & Third Party Inspection & Audit Services

TNV Certification Pvt Ltd



537-B/187-B, Amber Vihar, Nr-CBI, Keshav Nagar, Sitapur Rd., Lucknow-20 UP (India) Phone: 0522-2756327-328, Fax: 0522-2759881