

NUSTAR CERTIFICATION & INSPECTION PRIVATE LIMITED

B-53, TF, Sector 64, Noida, U.P., India

E-mail: info@nustarcertification.com, Website: www.nustarcertification.com

Client's Application Form

Thank you for choosing Nustar as your certification registrar. To ensure we provide the best service tailored to your needs, we kindly ask you to complete the attached questionnaire. Once completed, please return the document to:

Nustar Certification & Inspection Pvt. Ltd., Office A, B 53, 1st Floor, Sector 64, Noida-201301 (UP), India.

Or mail at: info@nustarcertifications.com

| | | |
|---|--|-------------------|
| Ref no:(For Office Use) | | |
| please select the correct option | | |
| <input type="checkbox"/> Initial certification <input type="checkbox"/> Transfer certification <input type="checkbox"/> Re certification <input type="checkbox"/> widening or reduction scope | | |
| Organization Details: | | |
| Name | | |
| Address | | |
| Audit site address: | | |
| Name of the organization's head: | | Designation: |
| Mobile/land line: | Email: | Website: |
| Legal status of the Organization: (Tick the correct one) Proprietorship/Trust/Society/Partnership firm/ Pvt. Ltd./Ltd. Company/ Govt. dept. | | |
| Contact person's name: | | Designation: |
| Mobile/ Phone: | E mail: | |
| Number of Total Employees: | | Number of shifts: |
| (if there is more than one audit site please give address of each site and no. of skilled/ unskilled personnel in each shift) | | |
| Management System standard to be audited: (Please tick Appropriately & fill relevant annex for specific information) | | |
| <input type="checkbox"/> ISO 9001:2015 | <input type="checkbox"/> ISO 14001:2015 (Please fill Annex-1) | |
| <input type="checkbox"/> ISO 45001:2018 (Please fill Annex-2) | <input type="checkbox"/> ISO 13485:2016 (Please fill Annex-3) | |
| <input type="checkbox"/> IMS (Please fill Annex-4) | <input type="checkbox"/> Transfer of certificate (Please fill Annex-5) | |
| <input type="checkbox"/> MDR 2017 | | |
| Scope: | | |
| Clauses not applicable if any (In case of QMS): | | |
| Product / service related, any legal/ regulatory requirement: | | |
| Date of Documentation: | Date of Last Internal Audit : | Date of Last MRM: |
| Information about the identified Risk under QMS (for Product / services causes life at risk, injury of illness, unlikely to cause injury or illness) to consumer/staff | | |
| Please provide key processes / functions & operations | | |

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*Details of Outsource Processes:

*Total No of Shifts:

*No of Personnel Permanent (Full Time):

*No of Personnel Contract based (Full Time):

*No. of Personnel (Part Time) with working hours details:

Total No of Personnel

*Do you operate at Temporary site?

If Yes, Then No. of Temporary sites:

| S.no | Temporary Site Location | Total no of Emp at Temporary site | Temporary site Activity. | Shift |
|------|-------------------------|-----------------------------------|--------------------------|-------|
| | | | | |
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*Are you using a consultant? If yes please specify name/ organization (With Mandatory Details):

Do you want to suggest any timing of the audit which will best demonstrate the full scope of the organisation? The consideration could include season, month, day/dates and shifts as appropriate. If yes please mention:

Applicant Sign :

(with Name and stamp)

Date:

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Annex 1

| | | |
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| Please provide the information related to Environment Management System | | |
| Date of Initial Environmental Management System Review of your activities, Products or services | | |
| Date of your Environmental Impact Assessment (EIA study/ Aspect-Impact analysis)? | | |
| Is there nearby any Surface water body like river/lake, Estuary / tidal water body, Protected nature conservation areas, Large Scale industry, Highway / Railway line/ Airport, Ground water which is sources of drinking water, Sea, Agriculture land / Forest Area, Human Habitation, Places of tourist attraction | | |
| Pollution category of your industry? Red / Orange/ Green / White / Exempted | | |
| Please provide the brief of emission details | | |
| *Please Answer the following Question specific to ISO 14001 | Please provide the information related to Occupational Health & Safety Management System | Activity |
| | Air Pollution | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Water Pollution | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Noise Pollution | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Land Pollution | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Resources Depletion | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Generation of Hazardous Waste | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Generation of Bio-medical Waste | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Consent to establish and operate. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Authorization for (handling & management) hazardous west | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Are all permits including state Pollution Control Board Consent/s in place? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Do you operate an ETP and or STP | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Have you received any notice / direction from Ministry of Environment & Forest / State Pollution Control Board in Last 5 years | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Is any environment related suit filed against you? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| any other relevant information pertaining to Environment | <input type="checkbox"/> Yes <input type="checkbox"/> No | |

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Annex 2

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|---|---|---|
| Please provide the information related to Occupational Health & Safety Management System | | |
| Have you conducted an Initial Review exercise to identify the OH&S Hazards | | |
| Date when hazard identification & Risk Assessment (HIRA) was done | | |
| Have you established ROR? | | |
| Date of OHSMS Implementation | | |
| *Please Answer the following Question specific to ISO 45001 | Please provide the information related to Occupational Health & Safety Management System | |
| | Physical Hazards[E.g. Acoustic Radiation, Temperature, Magnetic Radiation, Electromagnet Radiation, Radioactivity, Ergonomic Stress, Physical Impact] | <input type="checkbox"/> Yes <input type="checkbox"/> No If yes please specify |
| | Chemical Hazards [E. g. Asphyxiate, Combustible, Corrosive, Explosive , Flammable, Irritant, Pyrophoric , Organic Peroxide, Oxidizer , Water Reactive, Unstable/Reactive] Carcinogen, Mutagen ,Poison, Sensitizer, Teratogen ,Toxic Chemicals | <input type="checkbox"/> Yes <input type="checkbox"/> No If yes please specify |
| | Engineering Hazards | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Biological Hazards[E.g. hazards due to pathogens] | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Working on electrical equipment / electrical energy source | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Working at height | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Working in confined space | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Consent to establish and operate | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Authorization for (handling & management) hazardous west | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Are all permits including state Pollution Control Board Consent/s in place? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Do you operate an ETP and or STP | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Have you received any notice / direction from Ministry of Environment & Forest / State Pollution Control Board in Last 5 years | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Is any environment related suit filed against you? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
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Annex 3

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| *Please Answer the following Question specific to ISO 13485 | Is the product a nearly finished and assembled medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labelling) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the product intended to be a component/part of a medical device? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabelling, remanufacturing of other medical devices)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the product supplied sterile? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | | If "yes", Please mentioned: | |
| | Is the sterilization performed in house? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Does the product contain software developed by the client organization or a supplier? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is "Design and Development" in the scope of the ISO 13485 certification (e.g., when public law permits exclusion of design and development which is the case very often for low-risk medical devices)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Does the device require mains connection or batteries for operation? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Does the device feature a measuring function? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Does the device incorporate medicines or substances that may be used separately as medicinal products? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Does the device incorporate materials of animal origin? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the device mainly manufactured by Subcontractors? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the device placed on the market under your own name? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Has the device already gained any approval? If yes, which? (please include certificates) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | Is the device packed and/or sterilized externally? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the device non-sterile and intended to be sterilized at customer site? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| Do you maintain Cleanroom conditions? If yes, which classification (according to ISO 14644)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |
| Any confidential or sensitive information organization is unable to share copy (Please declare): | <input type="checkbox"/> Yes | <input type="checkbox"/> No | |

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Annex 4

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| *Please Answer the following Question specific to IMS | If you have opted for Integration Management System, Please fill below required information as a rating for level of integration of an organizations management system: | |
| | If Integrated management system is implemented then please provide the date since IMS is being implemented / IMS Manual issue date | |
| | Integrated Documentation (Manual, policy and objectives, procedures, work instruction etc.) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | An Integrated approach to Roles & Responsibilities | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Conduct of Integrated / approach to Internal Audit | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Conduct of Integrated Management Reviews considering the overall business strategy and plan | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | An Integrated approach to systems processes & continual Improvement mechanisms | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Organization's personnel to respond to questions more than one management system standards. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Annex 5

| | | |
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| *Please Answer the following Question specific to Transfer of certificate | Details of current Registrar/ Certification Body & Accreditation Board | |
| | Details of certified standard (s) including version, Date of validity, Reason of transfer | |
| | Are copies of your latest audit reports available | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | Do you have any complaints from customers currently in process | <input type="checkbox"/> Yes <input type="checkbox"/> No if yes please provide detail |
| | Do you have any open non-conformances from your existing Registrar, | <input type="checkbox"/> Yes <input type="checkbox"/> No if yes please provide details |
| | Are there any recent or current legal compliance issues that have your organization engaged in legal representation with statutory or regulatory bodies | <input type="checkbox"/> Yes <input type="checkbox"/> No if yes please provide details |