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# Hindustan Syringes, Niraj Industries get MDSAP certification

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**Becomes the first set of Indian Manufacturers of Disposable Medical Devices to achieve MDSAP certification**

The group companies of Hindustan Medical Devices- Hindustan Syringes & Medical Devices Ltd, one of the largest manufacturers of Disposable Syringes in the World and the largest for Auto Disable syringes and a strong advocate for Make in India for Medical Devices and Niraj Industries were among the first set of Indian Manufacturers of Disposable Medical Devices to be awarded the prestigious MDSAP quality assurance certificate.

The Medical Device Single Audit Program (MDSAP) allows a single regulatory audit of a medical device manufacturer's Quality Management System (QMS) which satisfies the requirements of multiple regulatory jurisdictions to address Patient Safety concerns.

Manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

For manufacturers, MDSAP is of benefit as it reduces the overall number of audits or inspections and optimizes the time and resources expended on audit activities.

MDSAP certificate aims to promote globally a greater alignment of regulatory approaches and technical requirements which are based on international standards and best practices. Additionally, it also promotes consistency, predictability and transparency of regulatory programs.

MDSAP certificate is an addition to ICMED (Indian Certification for Medical Devices) HMD received from QCI (Quality Council of India). ICMED Certification process allowed us to build competencies and confidence needed to strive for MDSAP - explained Rajiv Nath

“This tough certificate also endorses the robustness and world class quality assurance of HMD factories that produce disposable and auto disable syringes, insulin pen needles, and surgical blades among other devices, “Niraj Industries is dedicated to Surgical Blades & Scalpels and Hindustan Syringes is making the balance range of Disposables” - Rajiv Nath added.

Audits are conducted by Auditing Organizations (AO), such as UL, authorized by the participating Regulatory Authorities (RA) to audit under tough MDSAP requirements.

In India 23 Categories of Medical Devices are Regulated under Medical Device Rules 2017 under Drugs & Cosmetics Act. Manufacturers & Exporters need to comply with importing Countries Regulatory requirements to address importing Countries Patient Safety Concerns which also act as Market Access Trade Barriers. Manufacturers need to continually upgrade their manufacturing capabilities to address these Market Access Regulatory requirement that keep getting tougher by the day.