Operon Strategist has achieved CE Certification under EU MDR in Switzerland.

PUNE, MAHARASHTRA, INDIA, February 28, 2023 /EINPresswire.com/ -- Operon Strategist is the one of the first few in Switzerland to have assisted in CE Certification of Opthalmic giant. They are among first few companies in Switzerland to be certified for CE Marking in new regulation of EU MDR. Assessment and certification is completed by EU's Notified Body.

Achieves First MDR in Switzerland

CE marking is a certification mark that indicates that a product complies with the applicable European Union (EU) directives and regulations. In the case of medical devices, CE marking indicates that the device meets the requirements of the EU Medical Device Regulation (MDR) or the EU In Vitro Diagnostic Regulation (IVDR), depending on the type of device.

The mark serves as proof that the device meets the relevant safety, health, and environmental protection requirements, as well as any other applicable requirements set out in the regulations. Obtaining CE marking for medical devices can be a complex process that requires technical expertise.

The achievement of this certification sheds light on the continued dedication to provide best service in Medical Devices Industry globally. For the CE marking, manufacturers need to classify their product, identify the relevant EU standard and other health and safety checks, and prepare a technical file for submission. Manufacturers of medical devices requires such professionals and experts to deliver quality services for low and high-end patient care devices.

Currently Operon Strategist has expanded their footprint in more than 32 countries for delivering unmatched services for documentation preparation and trainings. Specially when EU MDR is becoming challenging for medical devices manufacturers. Hence, CE Marking Documentation and Submission from an expert becomes vital for any manufacturer

The EU-MDR(EU Medical Device Regulation 2017/745) replaced the previous EU-MDD (Medical

Device Directives 93/42/EEC). This updated regulations has strong impact on technical documentation, Clinical data and post market survillance.

CE marking enable your product and process to comply with global regulatory requirements allowing design, manufacturing, installation, service and engineering for the medical devices

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