ISO 13485 certification brings StrepSure® closer to market

Highlights:

- **ISO 13485 certification secured for the quality management system behind StrepSure®, covering its design, development and manufacture**
- **ISO 13485 is the international quality standard for medical devices, and a core requirement of regulators, hospitals and distributors, marking a significant step towards bringing StrepSure® to market**
- **Certified manufacturing positions Nexsen to supply StrepSure® to an internationally recognised standard as it prepares for launch in Asia-Pacific**
- **QMS meets the requirements of the Medical Device Single Audit Program ("MDSAP"), recognised by regulators including the US FDA and Australia's TGA**
- **Advances StrepSure® towards its FDA submission**
- **Established QMS provides a quality foundation for future devices across Nexsen's pipeline**

Nexsen Limited (**ASX:NXN**) ("**Nexsen**" or the "**Company**"), an emerging leader in rapid point-of-care diagnostics, is pleased to announce it has achieved ISO 13485:2016 certification for its Quality Management System ("QMS") covering the design, development and manufacture of StrepSure®, its Group B Streptococcus ("GBS") diagnostic, following assessment by global standards and certification body, the British Standards Institution ("BSI").

ISO 13485 is the internationally recognised quality management standard for medical devices, a core requirement for regulatory submissions and a standard expectation of commercial partners and distributors. In practical terms, certification puts in place the quality system Nexsen needs to progress StrepSure® from development towards regulatory approval and commercial supply, marking another important step in the Company's transition from research-led development towards commercialisation.

With manufacturing included within the scope of the certification, Nexsen is positioned to manufacture and supply StrepSure® under a certified quality system as it moves towards commercial launch. This is central to the Company's Asia-Pacific strategy, with Hong Kong as its initial commercial entry point and regional hub for manufacturing and distribution, and strengthens its position with distributors, hospital networks and commercial partners across the region, where ISO 13485 is widely recognised. StrepSure® is targeting a large global opportunity, with ~132 million births worldwide each year[1] underpinning a substantial testing opportunity.

The certification also supports StrepSure®'s path to the US market. Nexsen's QMS meets the requirements of MDSAP, which enables a single audit to address the requirements of multiple regulators, including the US Food and Drug Administration ("FDA") and Australia's Therapeutic Goods Administration ("TGA").

The benefits extend beyond StrepSure®. Having established and certified its QMS, Nexsen now has an operating quality system and documented processes and templates that can be applied to other products in its pipeline, including its kidney disease diagnostics. This provides a strong foundation for future products as they advance towards regulatory and commercial development, allowing Nexsen to build on infrastructure already in place.

Managing Director, Mark Muzzin, said:

"This is a major milestone for Nexsen and a significant step on StrepSure®'s path to market. ISO 13485 is one of the core requirements for selling a medical device, and achieving it across design, development and

[1] United Nations, World Fertility Report 2024.

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manufacture gives regulators, hospitals and partners confidence that StrepSure® is built within a quality system certified to an internationally recognised medical-device standard.

Having built and certified this system, we now have a scalable quality framework that benefits every product in our pipeline. With certification in hand, our focus is on our FDA submission and launch in Asia-Pacific."

-ENDS-

ASX release authorised by the Board of Directors.

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About Nexsen Limited (ASX: NXN)

Nexsen is developing a growing portfolio of rapid point-of-care diagnostics for serious conditions where delays in diagnosis can affect patient outcomes and limit the ability of clinicians to make fast, informed treatment decisions. The Company's lead programmes include diagnostics for Group B Streptococcus (GBS) in maternal health and kidney function, targeting Acute Kidney Injury and Chronic Kidney Disease. Together, these programmes address significant areas of unmet clinical need across large global patient populations. Nexsen is also advancing additional diagnostic programmes across traumatic brain injury, neonatal sepsis and biosecurity, supported by a growing international research, clinical and commercial network across Australia and Asia.

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