February 6, 2022
Uppsala, Sweden
Astrego Diagnostics AB

Astrego Diagnostics´ Quality Management System is Certified to ISO 13485:2016 for Medical Devices

Astrego´s Quality Management System was duly certified to the international standard for Medical Devices, ISO 13485:2016 on February 4th, 2022 following a two-stage audit process performed by the BSI Group The Netherlands B.V.

The scope of the certificate is *"Design, development and manufacture of in vitro diagnostic analysers and assays for bacterial infection and antibiotic susceptibility testing. Service of in vitro diagnostic analysers for bacterial infection and antibiotic susceptibility testing"*.

Commenting on the certification, Mike Read (COO) said "It gives me great pleasure to announce this milestone which marks the culmination of quality management work that has been ongoing and fundamental to the core of the company since our founding in March 2017. The wide scope of the certificate includes development and in-house manufacturing of our single use test cartridge and analyzer, together with analyzer service. This testifies to the breadth and maturity of the team that has been built over the five years since founding as we prepare to launch our first product for susceptibility testing in Urinary Tract Infections during 2022"

Visit https://www.astrego.se or https://www.linkedin.com/company/astrego/ for more information.