

## ASX Announcement

26 May 2022

### ISO 13485:2016

Analytica Ltd (ASX: ALT), manufacturer of the PeriCoach® system is pleased to announce that the company's quality management system has been certified by BSI to ISO13485:2016 for the design, development, production, sales and distribution of pelvic floor exercise aides.

The certificate of registration MD 751667 is effective 2022-05-20 and expires 2025-05-19.

ISO 13485:2016 is the international standard for quality systems for medical device manufacturers.

CEO Geoff Daly: "This is a major achievement for Analytica and acquiring this certification allows us to bring PeriCoach manufacturing in-house for global manufacture, giving us better control of the production process. The rapid acquisition of this certification is in no small part due to the excellent system developed by Analytica's Quality and regulatory team, especially Chelsea Cornelius, and our regulatory consultants.

Authorised for release by the Board.

For more information, please contact: [investorrelations@analyticamedical.com](mailto:investorrelations@analyticamedical.com)

For more information about the PeriCoach System, visit: [www.PeriCoach.com](http://www.PeriCoach.com)

For more information about Analytica, visit [www.AnalyticaMedical.com](http://www.AnalyticaMedical.com)

### About Analytica Limited

Analytica is a product development and commercialisation company, based in Queensland, Australia, focussed on Class I and II medical device products.

Analytica's lead product is the PeriCoach® System – an e-health treatment system for women who suffer Stress Urinary Incontinence. This affects 1 in 3 women worldwide and is mostly caused by trauma to the pelvic floor muscles as a result of pregnancy, childbirth and menopause.

PeriCoach comprises a device, web portal and smartphone app. The device evaluates activity in pelvic floor muscles. This information is transmitted to a smartphone app and can be loaded to a cloud database where physicians can monitor patient progress via web portal. This novel system enables physicians to remotely determine if a woman is performing her pelvic floor exercises and if these are improving her condition. Strengthening of the pelvic floor muscles can also potentially improve sexual sensation or satisfaction and orgasm potential in some women.

PeriCoach has regulatory clearance in Australia and has CE mark and USFDA 510(k) clearance for the treatment of urinary incontinence.

PeriCoach also has clearance in Australia, and CE Marking in Europe for the treatment of mild to moderate pelvic organ prolapse, a condition that affects up to 1 in 5 women during their lifetime.

Analytica is also the developer of the Enhanced Infusion System (EIS), a combination of patented technologies developed under the project names AutoStart and AutoFlush. The EIS is a simple and inexpensive IV add-in technology to reduce nursing monitoring costs, reduce embolism risk, improve infection control, and automatically restart flow after medication delivery during intravenous fluid infusion.