

# MED TECH

*OUTLOOK*

**IN VITRO  
DIAGNOSTIC  
EDITION**



JAN WILKE,  
MANAGING DIRECTOR

**A VANGUARD OF  
TURNKEY MEDICAL  
INSTRUMENTS**

# BIT ANALYTICAL INSTRUMENTS

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## BIT Analytical Instruments



*The annual listing of 10 companies that are at the forefront of providing In Vitro Diagnostic solutions and impacting the industry*

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# BIT ANALYTICAL INSTRUMENTS

## A VANGUARD OF TURNKEY MEDICAL INSTRUMENTS

**T**he medical device industry remains steadfast in its pursuit of delivering high quality, point-of-care diagnostic instruments to improve healthcare and save lives. Underpinning this mission is the robust and innovative manufacturing expertise of companies like BIT Analytical Instruments GmbH that ensures flawless and continuous improvement of product.

BIT's legacy spanning over four decades as a one-stop contract developer and manufacturer, positions it at the helm of the medical device industry.

The company specializes in offering services across the complete product lifecycle, from research, design,

development and manufacturing to after-sales and for high-performance in vitro diagnostic (IVD), medical and life sciences devices.

"We are very client-centric and provide lifetime support to keep the instruments alive," says Jan Wilke, managing director at BIT.

### **Innovation is the Key**

'Build Innovation Together' is not just in its name. BIT's unwavering mission is to help customers rapidly and efficiently launch novel and cost-effective products in their markets. With over 100,000 square feet of floor space in

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JAN WILKE,  
MANAGING DIRECTOR





Europe and China, its in-house manufacturing capabilities make it as a highly efficient outsourcing partner for building and servicing equipment.

It caters to a diverse clientele comprising large manufacturers, original equipment manufacturers (OEM), and agile medtech startups across hematology, immunology, clinical chemistry, and molecular and anatomical pathology segments. BIT designs and develops innovative instruments with high levels of customization, on an OEM or co-development basis.

For startups and smaller companies, budget constraints and tight timeframes are major concerns during the R&D phase.

Demonstrating a consistent track record of adherence to stipulated timelines and budgets, BIT provides clear guidance to clients from the project's outset. It leverages its deep consultative knowledge to jointly determine the 'non-essential' functions of their instruments that can be modified or deferred to later stages. This informed decision-making helps startups prioritize their crucial functionalities for the initial product release.

Client success stories demonstrate its commitment to project management that produces timely results.

MACRO ARRAY Diagnostics (MADX), a Vienna-based medtech company, was looking to develop and manufacture its flagship IVD multiplex allergy diagnostic device. The goal was to achieve an automated allergy testing platform that required minimal operator intervention while ensuring exceptional results.

BIT adopted a systematic approach to developing its instruments with the utmost quality and functionalities within the specified technical and budget constraints. Using in-house design solutions, effective planning and

strong communication, it delivered the project on time with reduced manufacturing costs.

The two IVD analytical devices BIT manufactured for MADX exceeded the client's expectations and became commercially successful in the market, which made it a foremost player in the allergy industry.

"Our project management capabilities set us apart. We are experienced enough to consistently deliver accurate and realistic timelines and budgets," says Thomas Eck, managing director at BIT.

### **Achieving Quality and Regulatory Excellence**

BIT's quality assurance and regulatory intelligence are also sought-after capabilities.

When larger companies embark on a new product launch, they face heightened scrutiny. They need to meet more stringent quality and regulatory standards compared to their smaller counterparts, due to more extensive operations for a broader consumer base.

BIT's seasoned experts possess an in-depth understanding of regulatory nuances, consulting on instruments with high-quality standards and compliant with in vitro diagnostic regulations (IVDR). They guide clients to achieve local regulatory requirements like CB certification and electromagnetic compatibility testing, as well as support their future shifts into global markets.

A collective focus on quality extends throughout BIT's teams, from R&D to those overseeing manufacturing processes. They excel at aligning their outputs, documents and processes with established frameworks, seamlessly adapting to various internal quality management systems.

BIT also caters to an increasing number of prominent clients seeking instrument updates due to obsolescence and cybersecurity concerns. They are reluctant to build a new instrument, given the success of their existing instruments in the market for many years or decades.

Based on its unparalleled experience working with numerous medical and IVD instruments, BIT offers comprehensive consulting services in upgrading firmware and components to defend against vulnerabilities. It strategically plans when to replace outdated PCBs, motors, and electronic components.

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"Our strength extends beyond consulting. We go the extra mile in implementing necessary tasks to prolong the lifecycle of an existing product," says Dr. Konstantin Christou, CTO.

When it comes to sourcing, the company is adept at identifying components with the highest likelihood of enduring in the market. This is a combined effort between its R&D and select regulatory-compliant supply chain vendors, to assemble reliable instrument parts with the lowest material costs and shortest lead times.

### **Pragmatic Consulting with a Difference**

BIT's horsepower in delivering an end-to-end service spectrum solidifies its position as a formidable partner in the medical device manufacturing landscape. Its 360-degree focus on projects, regardless of size or complexity, makes it highly trustworthy.

Beginning with feasibility studies, it provides prospective investors with critical evidence of product functionalities. Clients obtain a ballpark estimate of the cost and impact before the design phase. In unclear circumstances, they are educated on design needs based on the project's nature to identify the path that best fits their market demands.

Using its in-house 3D printing capabilities, BIT fabricates scaled-down models of new products from its portfolio of ready-to-use PCB boards, robotic arms, pumps and optical components. This rapid prototyping aids larger enterprises in outsourcing manufacturing and serves as valuable POC for startups seeking investor confidence.

BIT seamlessly transitions into the design phase. It develops complete instruments, along with adjustments to assay schedules, timings, temperatures and other applicable specifications.

Verification and validation are integral to BIT. A product prototype undergoes rigorous testing against the standard software requirements document framework. After finalizing the design, the prototype is transferred to the manufacturing unit.

This design transfer marks a critical phase, where BIT guarantees the instruments are serviceable and manufactured under optimal cost-efficient conditions. Guided by proficiency in instrument assembly, its engineers devise the most efficient production methods and modify the design strategies suitable for serial production. This enables clients to easily accommodate change requests and adjust product development at any stage, with a unified goal of meeting time-to-market objectives.

Last but not least, clients entrust BIT with complete service packages, including spare parts management, warehousing, and distribution, to maximize product performance.

### **Customer-Centricity at its Core**

Throughout its endeavors, the company infuses a customer-centric approach into its project planning capabilities. This dedication to customer satisfaction has fostered long-lasting relationships with renowned manufacturers like Siemens Healthineers, Abbott and Beckman Coulter, among many other industry leaders.

BIT's adaptability to evolving processes and client requirements, coupled with its financial stability, is a testament to its proven history of success.

The pillar supporting its integrity is a nimble team of over 230 employees well-versed in systems, software, electronics, mechanics, fluidics, and various technical domains of instrument development and manufacturing. They are well-equipped to meet usability requirements in design processes and are periodically trained in accordance with IEC 62304, the international standard that specifies life cycle requirements for software development in medical devices. This ensures the design aligns with the functional safety requirements.

A multidisciplinary team and a well-articulated vision to develop top-notch IVDR instruments enables BIT to continue to script success stories for its global customer base. 