

# Diagnostic Solutions

Keep track of your changing laboratory needs



# "Create Something Greater Together"

"A key part of our mission is to deliver comprehensive yet personalized diagnostics in the shortest possible time. Hamilton's automation solutions are essential to this, but even more important is the willingness to go the extra mile with excellent service and support to create something greater together."

Norbert Niklas, Blood Center for Upper Austria,  
Linz/Austria

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# Needs and Challenges of a Modern Clinical Lab

## HAMILTON'S AUTOMATION SOLUTIONS GROW WITH NEW CUSTOMER CHALLENGES

### Reduced Cycle Time

Automated diagnostic protocols save critical time: Patients receive a diagnosis quicker than before, assuring immediate treatment with high effect.

### Staff Enablement

With fewer skilled workers needed to complete repetitive tasks, employees can be deployed more flexibly and can perform more demanding and high-value analytical and data work-up tasks.

### Scale-Up Lab Throughput

Automating the complete testing workflow allows labs to scale and significantly increase output to meet higher or fluctuating demands.

### Data Connectivity and Data Integrity

LIMS connectivity enables easy and secure exchange of data from the automation systems for further processing, and to yield traceable documentation.





# Supporting Compliance Needs

**LEGAL REQUIREMENTS ARE SIGNIFICANT HURDLES - WE EMPOWER YOU WITH OUR SOLUTIONS TO OVERCOME THEM**

## **In-Vitro Diagnostic Regulation**

The In-Vitro Diagnostic Regulation (IVDR) of the European Union sets a legal and regulatory framework to ensure patients' safety and increase product quality. To place their products on the market in the EU, manufacturers are faced with more comprehensive requirements for the CE marking of their IVD devices:

- New risk-based classification (Class A-D), based on clinical risk profile
- More requirements for Technical Documentation
- New identifier: Unique Device Identification (UDI)
- New Post-Market processes (e.g. Post-Market Surveillance)
- Increased monitoring by Notified Bodies

## **Laboratory-Developed Tests**

Be it rare diseases or in-house optimized analysis solutions: Laboratory-Developed Tests (LDTs) play a tremendously important role in supporting healthcare facilities in diagnostic laboratories. LDTs developed, manufactured, and performed in a single laboratory are important niche products to ensure patient safety even in very dynamic fields of diagnostics (e.g., rare diseases, cancer) that cannot be served by traditional class B, C, or D IVD products.

## **Patient Safety – IVDR's Goal**

- Transparency
- Traceability
- Adaptation to new requirements

# Sample and Process Safety

## DIAGNOSTIC SAMPLE PREPARATION AND PROCESSING - RELIABILITY WITHOUT COMPRISE

### Automatic Loading and Scanning

Automated scanning of primary samples and labware during loading ensures the correct arrangement and the completeness of input material and labware.

### Sample Integrity

Storing samples and reagents under optimal conditions is critical for consistent results; whether short- or long-term storage, sample integrity is essential.

### Sample Monitoring

Never lose track of your samples, thanks to sample tracking, and ensure the availability of all required fill levels before each run.

### Superior Pipetting Technologies

Industry-leading liquid handling technologies guarantee safe and accurate pipetting of your valuable samples and provide more reproduceable (hence, more reliable) results. Assay sensitivity and specificity should benefit from state-of-the-art technologies.





# Monitor the Process, Mitigate Risk

## SAFETY FOR SAMPLES AND LABORATORY PERSONNEL - AUTOMATION OFFERS YOU BOTH!

### **Minimize the Risk of Human Error**

Always focused, never distracted – Automated Liquid Handlers pipette accurately and safely, even after hours and days of operation; it is a secure path to avoid cross-contamination and inaccurate sample handling.

### **Supervision**

Modern robotic platforms allow for the automated monitoring and documentation of each step in the sample handling process through innovative software and hardware functionalities. Stay ahead of your process!

### **User Safety**

Keep your employees safer by putting the automated pipettor in charge of handling potentially dangerous samples and injuries, due to manual pipetting tasks.

### **Relieve your Employees**

Reduce the workload of your lab staff and minimize the risk of inaccurate results: let the automated system pipette demanding protocols such as 384-well plates!

### **Smart Error Handling for Optimized Turnaround Times**

Modern Automated Liquid Handlers have integrated smart error handling technologies. Those technologies allow for the optimal processing of samples to minimize user returns and automatically solve unexpected errors.

# Hamilton's Product Portfolio

FOR DIAGNOSTIC LABS

## Guarantee your patients the highest quality results

Hamilton offers a broad range of Automated Liquid Handling Workstations, covering a wide range of demanding workflows in diagnostic laboratories. Our workstations are based on the proven Hamilton liquid handling platforms that feature cutting-edge technologies.

Developed and manufactured according to our high-quality standards, laboratories can rely on our workstations to achieve optimal processing time, highest process, and sample safety to mitigate risk and comply with regulatory requirements.



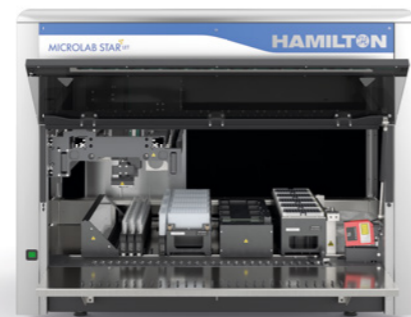
# Product Portfolio Overview

- ONCOLOGY
- CARDIOLOGY
- CLINICAL DIAGNOSTICS
- IMMUNOLOGY
- INFECTIOUS DISEASES
- REPRODUCTIVE HEALTH

Find the right liquid handling solution for your application - from primary blood sample handling to NGS library preparation. Learn more about existing automated protocols from various manufacturers, benefit from customer experiences, and find more background information on the featured device.

Highlighted, you will find the classic fields of application in which the respective automation solution is traditionally used.

For more in-depth information, scan the barcode and visit the Hamilton homepage.

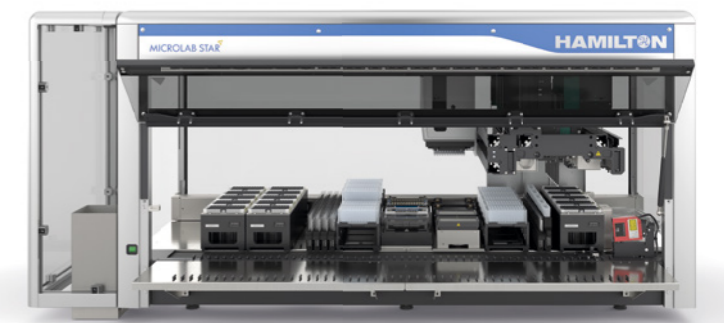


 **Aliquot STARline**  
For Primary Sample Processing

 **easyBlood STARline**  
For Blood Sample Fractionation

 **NIMBUS Presto**  
For Nucleic Acid Extraction and  
for Protein Extraction

 **MagEx STARline**  
For Nucleic Acid Extraction



 **Clinical NGS STARlet** IVD  
For NGS Library Preparation

 **VeriSeq NIPT STAR** IVD  
For Non-Invasive Prenatal Testing



# Aliquot STARline

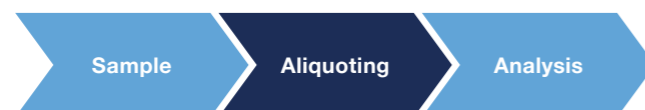
ONCOLOGY  
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## SAMPLE PRE-PROCESSING IN NO TIME

Pre-processing of blood sample tubes is a very tedious and monotonous task: tubes must be uncapped, aliquots transferred, and the tubes resealed.

Instruments from the new Aliquot STARline perform this task exactly, precisely, and safely. They simplify your daily work, offer complete sample safety, and eliminate the risk to laboratory staff when handling potentially life-threatening samples. And all this happens under constant process tracing by various technical solutions.

- Flexibility is key: Define your deck according to your needs
- Process safety and security assures precise and reliable results
- Tube-to-tube or tube-to-plate – you decide what to transfer and where
- Trace your samples during the entire process



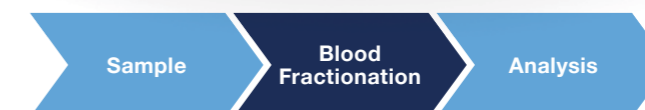
# easyBlood STARline

ONCOLOGY  
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## FULLY AUTOMATED BLOOD FRACTIONATION

Analysis of blood most often starts with blood fractionation. The easyBlood Assay Ready Workstation automates the blood-fraction separation process and increases the reliability and accuracy of both fraction detection and pipetting. The need to prepare blood samples for either storage or post-processing steps with high test capacity is greatly alleviated. This caters to the demands posed by biobanks and clinical laboratories.

- High resolution camera-controlled blood fractionation detection
- Reliable recognition and safe separation of the three fractions; red blood cells, buffy coat, and plasma
- Sample safety via dedicated liquid classes
- Pre-defined methods for quick adoption in your laboratory



# MagEx STARline

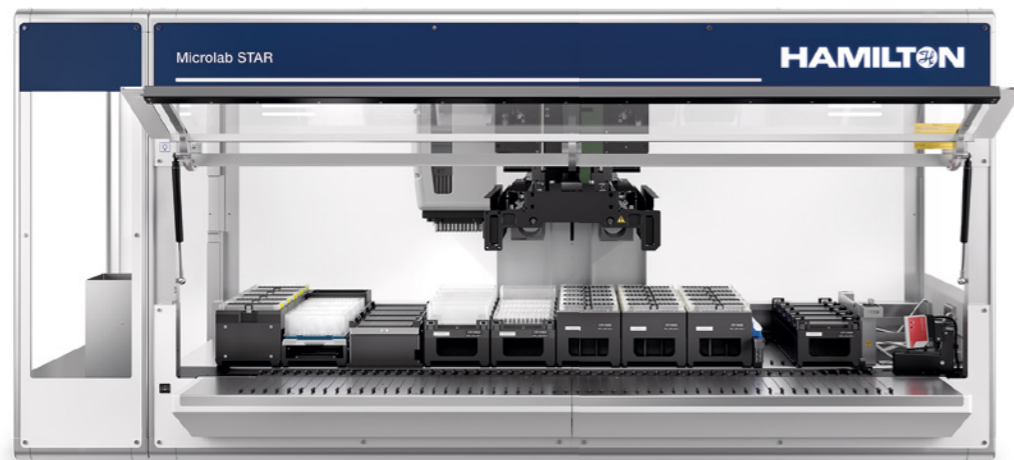
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## NUCLEIC ACID - EXTRACTION

The MagEx STARline is a fully automated solution for magnetic bead-based nucleic acid extraction - well proven to be the ideal instrument for isolation of pathogen RNA from Coronavirus (COVID-19).

It is designed for use with a variety of chemicals and protocols. These include home brew assays as well as FDA-approved protocols from leading partners. The configurations are designed for middle (MagEx STARlet) and high-sample capacity (MagEX STAR), to fully automate parallel nucleic acid extraction, from 8 samples to up to 4 times 96-well plates.

- Tried and True, Off the Shelf, Market Leading Platform for Covid-19 extraction
- Independent channels and MPH-96 ensure easily scalable throughput from 8 to 384 samples
- Flexible system for fast changing needs, open for different labware and magnets
- Well proven instrument for high test capacity in magnetic bead-based nucleic acid extraction



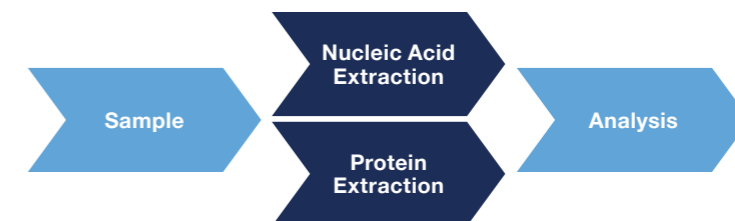
# NIMBUS Presto

ONCOLOGY  
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## NUCLEIC ACID - OR PROTEIN EXTRACTION - MADE EASY

NIMBUS® Presto is a flexible solution for a variety of applications, test capacity, and reagent needs. Combination of ML NIMBUS with KingFisher Presto results in a powerful tool for sample purification. Extracting 24 or 96 samples at a time with a wide volume range, NIMBUS® Presto is capable of DNA, RNA, cfDNA, and protein extraction from many biological sources.

- Interchangeable magnetic heads for processing 24- or 96-well plates
- Parallel processing of plates via turntable increases test capacity and saves time
- Targeted molecules can be extracted from various input material (Blood, FFPE, Saliva, Sputum)
- Fully enclosed, lockable system with compact footprint



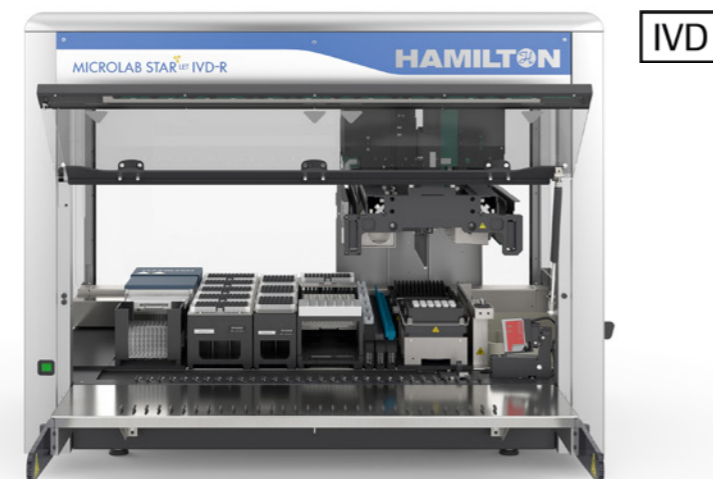
# Clinical NGS STARlet

ONCOLOGY  
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## NGS LIBRARY PREPARATION

Automating the library preparation process has become a pivotal element in NGS, addressing the requirements for usability, reproducibility, traceability, and safety needs, especially for smaller-sample batches. Hamilton's NGS STARlet is the ideal automated library preparation system for high-priority samples and small-to-mid-size sample test capacities of up to 24 samples.

- Instrument fulfills the requirements of IVDR
- Flexible system for rapidly changing needs, open for different labware and magnets
- Fully equipped sample-to-result solution (On-Deck Thermal Cycler, PCR comfort lid, plate transport via i-SWAP and CO-RE® Gripper, Heater Shaker and magnetic stand)
- Compact footprint



IVD



# VeriSeq NIPT STAR

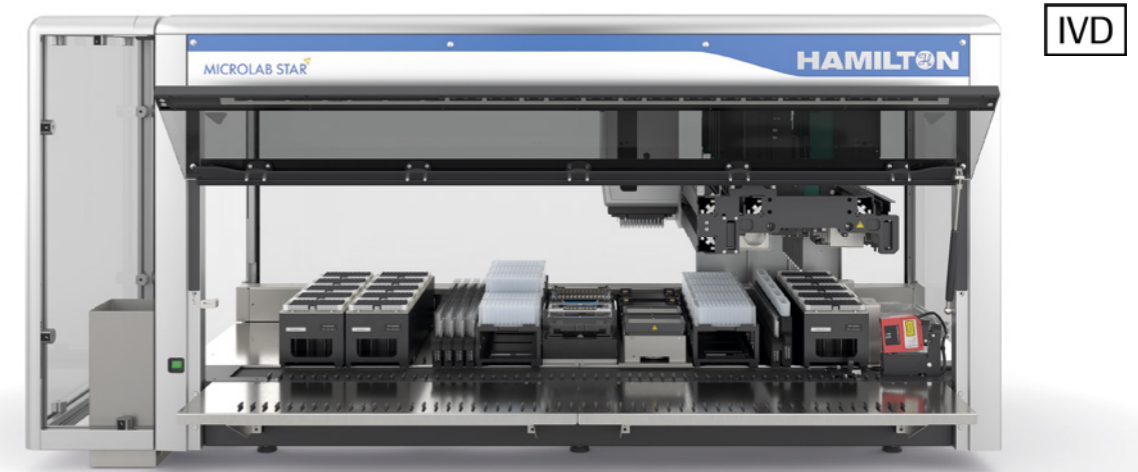
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## PRENATAL SCREENING



Hamilton and Illumina, Inc. have collaborated to provide an automated solution for clinical labs and healthcare systems performing clinical prenatal aneuploidy screening. This automated Next-Generation Sequencing (NGS) workflow, also known as Massively Parallel Sequencing (MPS), uses a PCR-free whole-genome approach to increase sample throughput and reduce turnaround time while greatly reducing the risk of human error and sample contamination. The Veri Seq NIPT solution combines the Hamilton Microlab® STAR with Illumina's proven NGS technology and software to create an automated and reliable solution for in-house, NGS-based NIPT that can screen for specific chromosomal abnormalities.

- Highly efficient solution for prenatal testing, based on a simple maternal blood draw
- Simple and scalable; easy-to-implement solution for 24, 48, or 96 samples per run
- Detects fetal aneuploidy and autosomal duplications and/or deletions using cell-free DNA (cfDNA)
- Instrument and methods validated in accordance with CE-IVD



IVD



# Hamilton's IVD Portfolio

## GO WITH THE TIMES!

We are proud to present our IVDR-compliant solutions for the diagnostic market that comply with the regulated framework within the EU. With decades of experience in development, as well as in the global market, we have access to a wealth of know-how and expertise. Our mission: highest product quality and long-lasting reliability, followed by truly customer focused field support. With our certified expertise and quality to With decades of experience in development, as well as in the global market, we have access to a wealth of know-how and expertise. Our mission: highest product quality and long-lasting reliability, followed by truly customer focused field support. Our certified expertise and quality to develop excellent devices, follows the credo: **“We drive innovation to improve people's lives.”**

Our sales representatives would be happy to provide you with additional information about our Diagnostics IVDR-compliant solutions.

### IVDR-compliant Solutions

Basic instruments, approved as Class A IVD devices, allow for the automation of any kit, up to Class D applications.

### IQ / OQ Documentation

Each laboratory automation system provides the required documentation and contributes to a good relationship and exchange with regulators.

### Software

Our state-of-the-art VENUS Software simplifies automation while delivering powerful and accurate results.

### We Consult and Support

From the first contact to the fully implemented application: Our experienced and motivated sales, applications, and support teams are committed to make sure you are successful with the new Hamilton system in your diagnostic lab.

### Hamilton Solutions

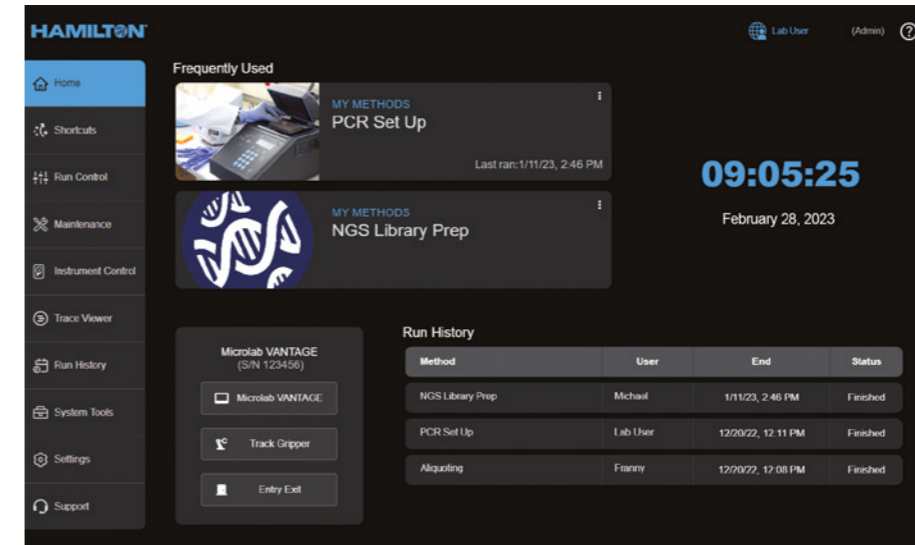
- ML STAR and STARlet IVD-R
- Clinical NGS STARlet
- IVDR-compliant consumables

### Important to Know

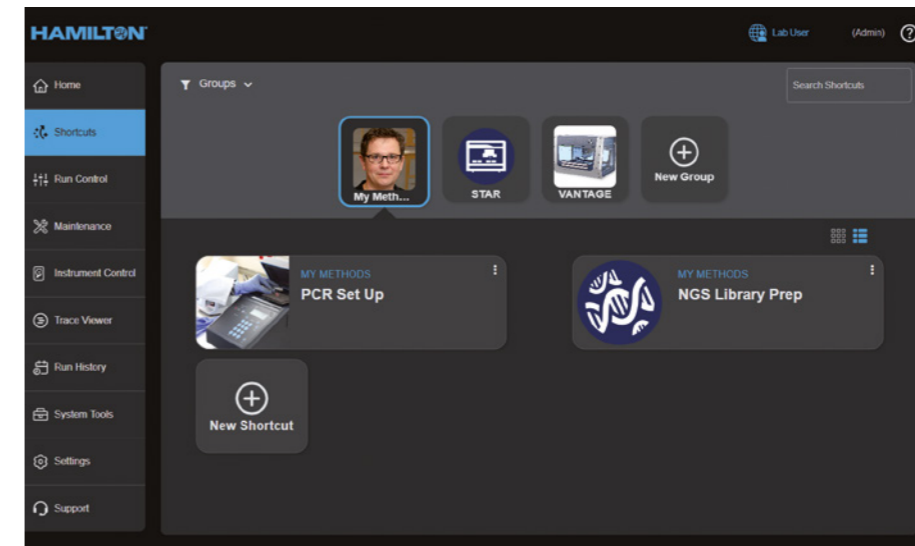
- Contact your Notified Body for binding clarification of important regulatory issues
- Registration and validation of the method (Class B and higher) is the responsibility of the customer

### Regulatory Support

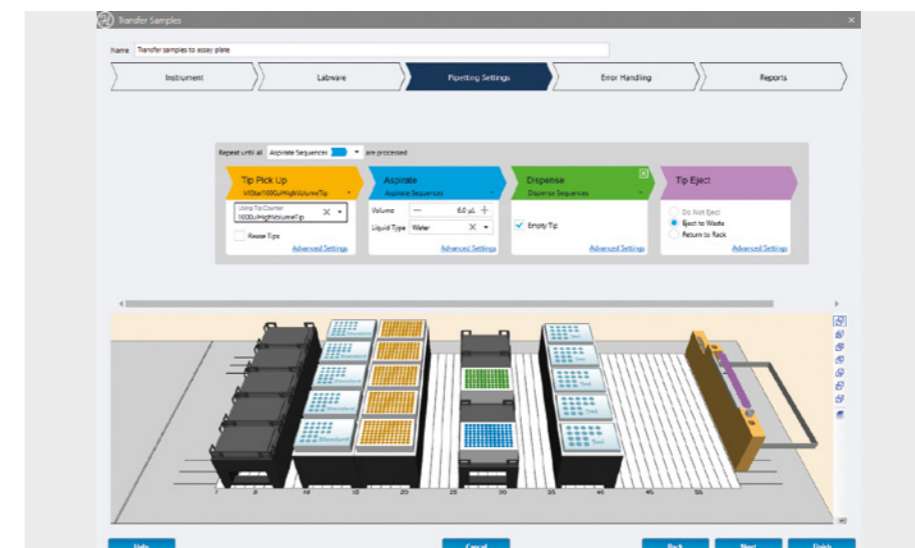
- Prepared and Guided Documentation
- Elaborated PMS plan
- Meet our Diagnostic Sales Specialists



Discover a seamless navigation experience with the all-new main interface of VENUS. The touchscreen-friendly cockpit view provides easy access to crucial information and functions at your fingertips. These include: frequently used methods, run history, and status of the connected system.



Get organized and save time with the new Shortcuts menu. Create custom shortcuts to your frequently used methods, group them into folders, and personalize them with a variety of included icons and photos. You can even upload your own images to make it truly your own.



Streamline your workflow creation process with Power Steps in VENUS. Select from a variety of templates for common pipetting tasks, and easily customize specific parameters such as volume and liquid type with the intuitive visual guide. Simplify your work and save time with Power Steps.

# Laboratory-Developed Tests

## EXPAND YOUR OFFER

Be it rare diseases or in-house optimized analysis solutions: Laboratory-Developed Tests play a tremendously important role in supporting healthcare facilities in diagnostic laboratories. LDTs developed, manufactured, and performed in a single laboratory are important niche products to ensure patient safety, even in very dynamic fields of Diagnostics (e.g., rare diseases, cancer) that cannot be served by traditional Class B, C, or D IVD products.

### Definition

- EU legislator regulates LDTs for the first time with EU regulation 2017/746
- Most regulations are not new, but now binding
- Additional requirements restrict use of LDTs

### Less Restricted – More Flexible

- If applicable, LDTs offer more degrees of freedom
- Ideal solution for rare diseases
- Highly-dynamic markets (e.g. Cancer diagnosis) can be addressed

### Support by Hamilton

- Every Hamilton instrument can be used for LDT applications
- Existing protocols can be applied on Hamilton automation solutions

### Requirements

- Meet Annex I GSPR
- Manufacturing must be done in-house and may not be made on an industrial scale
- Lab must comply with ISO 15189
- LDT must be superior to commercially available kits

## BENEFIT FROM HAMILTON'S BROAD FIELD OF APPLICATIONS

Out of Hamilton's automated solutions portfolio, we provide you with a dedicated and qualified liquid handling solution for your specific LDT. Analyze samples efficiently, safely, and effectively to help patients in a targeted manner, and in the shortest possible time.



# Proven Technologies for a Safe and Efficient Lab



## CO-RE II – TIP/TOOL ATTACHMENT

For the gentle grip

The new CO-RE II technology assures more precise tip alignment, minimizing the risk of collisions. In addition to tips, coupling is faster which boosts productivity.

Besides tips, a wide range of Hamilton tools are applicable with CO-RE II.



## AEROSOL – FREE TIP EJECTION

To prevent cross-contamination

CO-RE II technology enables force-less tip pick-up and eject, eliminating the risk of aerosol production and possible contamination.



## AUTOLOAD

For convenient identification

Eliminate manual errors with barcode-equipped Autoload and automatically detect and load deck equipment, while also scanning barcodes for complete sample tracking. Keep track of tip type and batch number with ease, ensuring accuracy in every step of your work.



## CO-RE GRIPPER

For additional movements

The CO-RE Gripper streamlines workflows by transforming channels into a plate gripper, adding the capability for on-deck transports of plates and tip racks. This feature allows for more hands-free time, as plates can be effortlessly moved to an incubation position, enhancing the overall efficiency.



## DPS – DYNAMIC POSITIONING SYSTEM

For efficient movements

DPS enables simultaneous pipetting of all channels even at irregular patterns, thus ensuring efficient liquid handling, unlike systems with fixed channels.



## DUAL LLD – DUAL LIQUID LEVEL DETECTION

For accurate aspirations

Conductive and pressure-based LLD systems can detect the surface of any liquid. Dual means:

Conductive and pressure-based LLD. This industry-leading technology assures that the surface of any liquid is detected safely and quickly.



## PLATE GRIPPER

For flexible integration

With a Plate Gripper, plates can be transported and fed to additional devices that extend the functionality of the system.



## MAGPIP

For cutting edge Liquid Handling

The tubular linear drive inside our MagPip channels can accelerate at speeds that enable precise and ultra-fast pipetting, down to 350nL. For research use only.



## MAD – MONITORED AIR DISPLACEMENT

For unmatched reliability

Monitored Air Displacement pipetting acts like a second set of eyes for all pipetting steps. It also ensures that the liquid has been aspirated correctly.



## TADM – TOTAL ASPIRATION AND DISPENSE MONITORING

AI-based technology for the utmost in safety

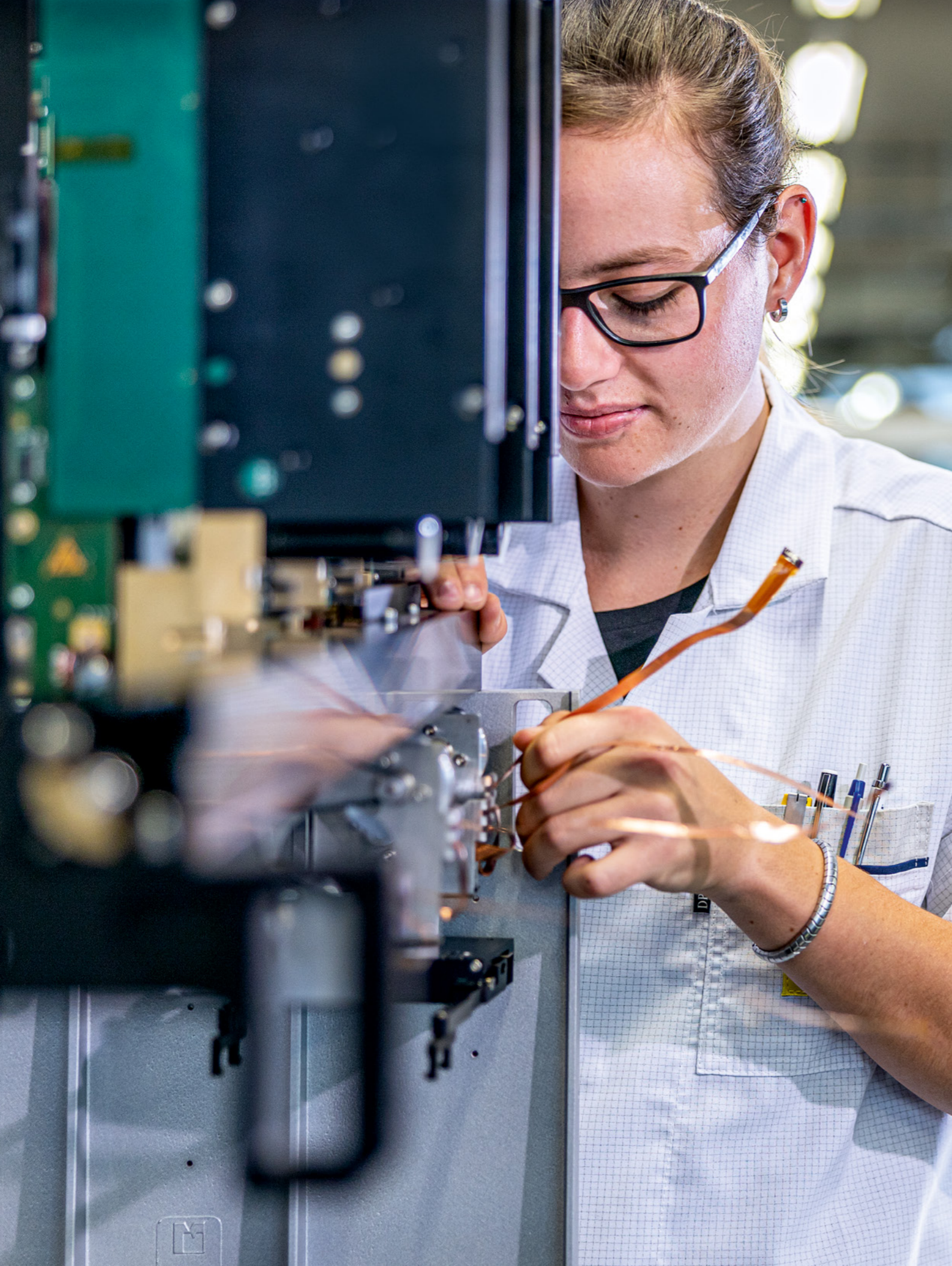
TADM can detect even the smallest deviations from expected aspiration and dispense steps, ensuring results that you can trust.



## SCALABLE SYSTEM

To safeguard your investment

Modern labs have to quickly adjust to changing requirements. Scalable Hamilton systems make it easy to increase capacity or add new functionalities.



# Industry-Leading Support

## SERVICE & SUPPORT YOU CAN COUNT ON

Our worldwide Service organization strives to provide the best service and support in the industry. Local engineers are trained by our Hamilton-certified trainers and supported by Service centers and distributors. Our commitment to high-quality standards goes beyond ISO 9001 certification and includes continuous training of all authorized service technicians. You can always rely on Hamilton for industry-leading service and support.



### EXTRA-MILE SUPPORT

- **Always there when you need us**  
Our global field service and support network - from the technical support hotline to local service engineers and application specialists - guarantees a fast response to your request and minimizes downtime. Whether routine maintenance, service support, or application support, the Hamilton team ensures your lab will be back up and running as quickly as possible.
- **Training makes perfect**  
Hamilton offers customers in-depth training sessions to ensure laboratories know how to properly use their automated handlers. Whether a general overview of your equipment at a Hamilton facility or personalized sessions in your lab, we are committed to setting your team up for success.



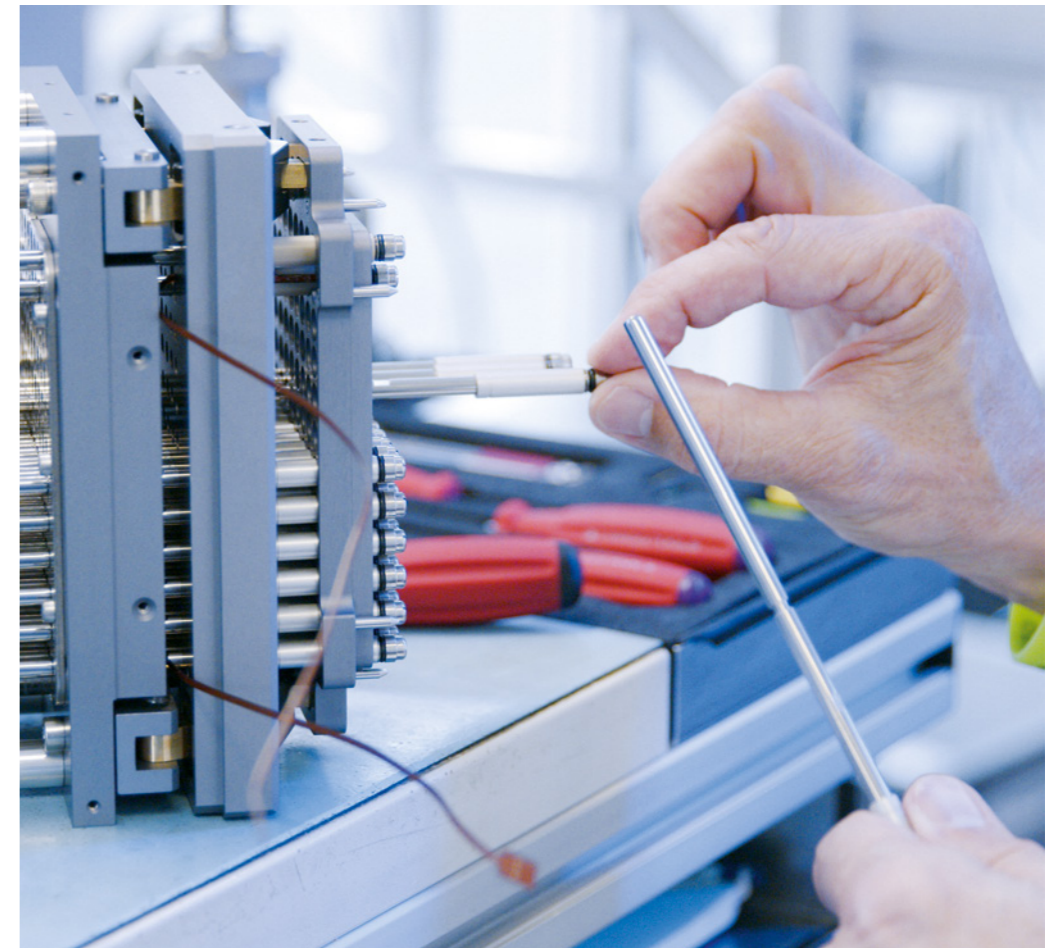
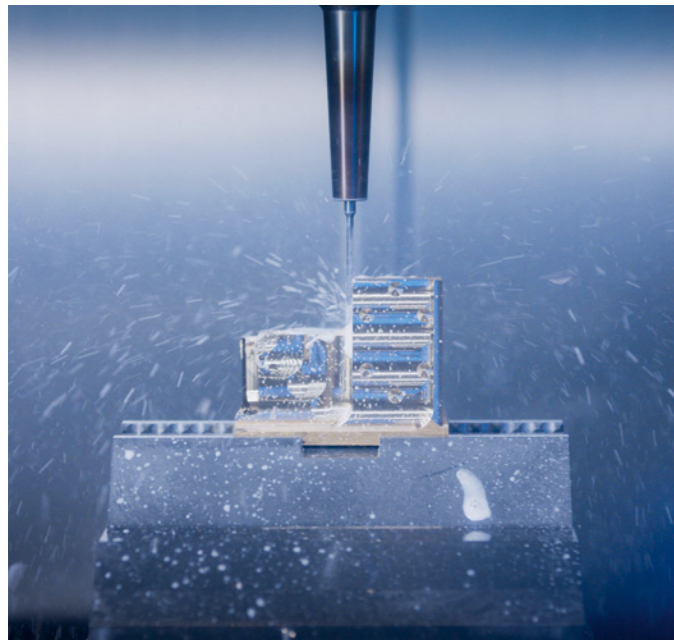
### HIGHEST QUALITY LEVEL AND THE BEST SERVICE

- **Quality from a single source**  
We guarantee the highest standards of quality, reliability, and precision for all our products, from our own production and state-of-the-art quality control systems to final inspection.
- **System installation made to measure**  
All Hamilton systems are installed according to strict procedures and in accordance with ISO 9001. Every system includes a comprehensive Installation Qualification (IQ) and detailed documentation.
- **Service as individual as you are**  
Ensure the longevity and peak performance of your automated system with a Hamilton service contract, including regular monitoring and preventative maintenance.

# In-House Production

Top-quality products, all under one roof. Hamilton takes pride in its in-house production capabilities, allowing us to maintain high-quality standards and quickly adapt to an ever-changing market. In addition to developing our own software systems, Hamilton produces CNC parts and pipetting tips. Trust Hamilton to create the ultimate solution for your lab.

Hamilton understands the importance of dependability. That's why we are committed to providing our customers with the product support they need. From in-house parts to creating customized solutions tailored to meet your needs, rest assured you're in good hands with Hamilton.





# Consumables

## ESSENTIAL FOR SAFE AND RELIABLE LIQUID HANDLING

Consumables are the essence of every workflow. That's why Hamilton offers a wide range of high-quality consumables that provide security, efficiency, and convenience. Our tips are made in-house, guaranteeing the Hamilton standard of quality and availability.

- Automated cleanroom production
- Automatic digital image processing inspections
- Complete, documented traceability

### Tips are manufactured to the highest quality standards:

- Production areas in accordance with ISO-14644-1 (Class 8)
- Quality Management System in accordance with ISO 9001, ISO 13485, 21 CFR 820 (FDA Quality System Regulation) and EU In Vitro Diagnostics Directive
- Sterile CO-RE tips manufactured in accordance with ISO 11137-1, ISO 11137-2, and ISO 11137-3



# Automating Your Imagination

«We drive innovation to improve people's lives»

## Hamilton Robotics

Hamilton Robotics is the industry leader in the development and production of state-of-the-art automated liquid handling systems and technologies. We drive innovation in laboratories around the world, turning concepts into realities. Our products are characterized by maximum reliability, efficiency, flexibility, and ease of use. From production to service to support, Hamilton's focus is always on your individual needs.

## Hamilton

Hamilton has been at the forefront of Life Science and Medical Technology for over 70 years. Our journey began as a visionary concept, transforming into a global company today. Though we've grown, Hamilton's passion, curiosity, and innovative spirit have never wavered. We remain committed to researching, developing, and producing cutting-edge solutions that improve people's lives.

**HAMILTON**

THE MEASURE OF EXCELLENCE



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Email: [infoservice@hamiltonrobotics.com](mailto:infoservice@hamiltonrobotics.com)

**United States**

+1-775-858-3000

**United Kingdom, Ireland**

+44 121 272 92 80

**Brazil**

+55 11 95914 5000

**China**

+86 21 6164 6567

**Denmark, Norway, Sweden, Finland**

+46 8410 27 373

**France**

+33 184 008 420

**Germany, Austria, Switzerland**

+49 89 248 804 804

**Benelux**

+31 40 209 178 0

**Italy**

+39 039 930 06 06

**Japan**

+81 3 6435 6850

**Spain, Portugal**

+34 930 186 262