

Two years of IVDR: membraPure draws a positive initial conclusion for itself and the users of its amino acid analyzers

The Amino acid analyzer ARACUS is Risk Class A certified and used globally in in-vitro diagnostics. membraPure GmbH understands the certification benefits.

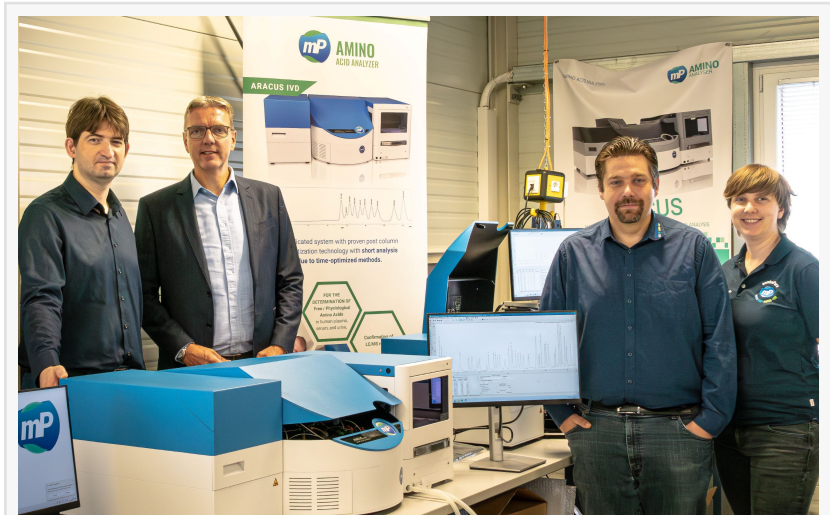
HENNIGSDORF, BRANDENBURG,
GERMANY, July 16, 2024

[/Einpresswire.com/](https://www.einpresswire.com/) -- Amino acid analysis remains a key component of modern diagnostics. Advanced analyzers like ARACUS classic and advanced are used in various fields, from medicine and research to the food industry, delivering increasingly precise results. However, this precision raises the standards for the systems used, particularly in medical applications, as reflected in regulatory requirements. Previously governed by the IVDD (Directive 98/79/EC), the IVDR (Regulation (EU) 2017/746 on in-vitro diagnostics) took effect on May 26, 2022, after a five-year transition period, requiring certification by risk classes for in-vitro diagnostic products. The ARACUS classic and advanced analyzers have been certified for IVDR Risk Class A since 2022 and are successfully used in Germany.

The IVDR imposes higher demands on products and manufacturers, increasing the workload. Two years after its implementation, membraPure's leadership can affirm that this effort has paid off in many ways: for laboratory work, for the global market opportunities of European medical products, and most importantly, for patients, ensuring high-quality analyses.

Dr. Jessica Walkowiak, Laboratory Manager:

“The certification brought structural changes: some processes now take longer due to more quality steps. However, our experience shows these steps integrate well into daily lab work, making processes more transparent and safer—a definite quality gain, even for non-medical



Drawing a positive conclusion about the IVDR: Sales Representative Dr. Thorsten Heinlein, CEO Dr. Erdmann Flindt, COO Dr. Carsten Stollfuß, and Laboratory Manager Dr. Jessica Walkowiak.

products.”

Dr. Erdmann Flindt, CEO of membraPure:

“We were the first to achieve this certification for these devices. Being pioneers helped us attract customers. Our devices' successful use confirms the correctness of pursuing IVDR certification. Besides medical users, those in the food industry and research also benefit from our high-precision analyzers.”

Dr. Carsten Stollfuß, COO of membraPure:

“Complaints about new regulations are common, but I must say: the IVDR benefits everyone. Product certification provides users with security. Because our ARACUS classic and advanced have this certification, users choose them, justifying our effort and enhancing our learning for future certifications. For instance, certifying our devices for non-EU markets will show significant synergies.”

Dr. Thorsten Heinlein, Sales:

“With the IVDR Class A certification of the ARACUS classic and advanced, we offer our customers a solution that meets all requirements, allowing them to focus on their work instead of regulatory details. Certification is a crucial decision aid, as our experience shows.”

For more information on the ARACUS amino acid analyzers and their applications, visit www.membrapure.de.

Dr. Thorsten Heinlein

membraPure GmbH

+49 3302 2012016

t.heinlein@membrapure.de

Visit us on social media:

[Facebook](#)

[X](#)

[LinkedIn](#)

[Instagram](#)

[YouTube](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/727952381>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2024 Newsmatics Inc. All Right Reserved.