

Customer information

Kammerstein, 15th January 2024

Successful MDR certification



Dear customers,

We are very pleased to inform you that our company has successfully passed the certification according to the Medical Device Regulation (MDR) of the European Union. From 15.01.2024, our product groups breathing gas humidifiers, heated breathing sets and humidification chambers will be produced and marketed in accordance with the MDR (Regulation EU 2017/745) in compliance with the latest European regulations.

The MDR certification not only marks a significant milestone in our efforts to offer high-quality and safe medical devices, but also brings significant changes to the labeling of our products. In order to meet the new regulatory and normative requirements, we have revised the labeling of our products in terms of language, symbolism and content. The updates comply with the latest EU regulations and have been carefully designed to meet the highest quality and safety standards.

While these selected product groups have been successfully transitioned to the MDR, we would like to point out that the other product groups will temporarily continue to operate under the familiar Medical Device Directive (MDD - Directive 93/42/EEC) until they have also been successfully transitioned to the MDR.

Our commitment to the highest quality and safety remains unchanged. We are working intensively to adapt the remaining product groups to the requirements of the MDR as quickly as possible.

Customer information

We would like to thank you for your continued support and trust. WILAméd remains committed to providing excellence in the medical device industry and continuing to offer you first-class products.

Please do not hesitate to contact us for further information or questions. We look forward to continuing our partnership and celebrating successes together.

Yours sincerely,

WILAméd GmbH