



Press Release

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With a dedicated product portfolio and expert support, Henkel helps manufacturers fulfill EU Medical Device Regulation certification requirements

Getting ready for MDR: Henkel sets dedicated program and develops adhesives to enable compliance for manufacturers of hygiene medical devices

Düsseldorf – The European Union’s MDR (Medical Device Regulation) is ushering in a new era of supply chain transparency and higher standards of safety for products used in the healthcare sector. While welcome, the introduction of MDR presents challenges for hygiene product manufacturers whose products are now classified as medical devices. From end of May 2021, all incontinence products have been classified as “class 1 medical devices”, with products currently on the market requiring recertification by 2024. For many manufacturers, this process may require more stringent quality management and traceability for products and their component materials than previously. Yet, this transition needs not be burdensome: As a leading supplier to the healthcare and hygiene sectors, Henkel is helping its customers ensure their products are ready for MDR. This is particularly important, as adhesives are key components of hygiene products and highly relevant regarding this compliance.

“To ensure MDR compliance, manufacturers require unprecedented visibility into their supply chains to ensure the safety and traceability of materials,” says Eilyn Meneses Villabona, Market Strategy Manager Personal Hygiene Adhesives EIMEA. The leading adhesives supplier supports manufacturers achieve MDR compliance with the following:

A Tailormade Portfolio: Henkel’s MED range of hot melt adhesives provides reliability and transparency for class 1 devices manufacturers. For bio-compatibility, all adhesives have passed ISO10993-5 & -10 cytotoxicity testing.

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Quality Management System: All adhesives are manufactured in ISO 9001 approved plants. Henkel's dedicated hot melt adhesives portfolio for adult incontinence products, the MED range, is characterized by an excellent quality, performance and processability. This ensures stability over time, long shelf life and low odor – thereby fulfilling the demands and requirements of the medical industry. With a conscious selection of raw materials, suppliers and production facilities, Henkel ensures highest standards of purity, proven by ISO10993-5 and ISO10993-10. A robust quality management process, leading plant systems and the frozen formulas approach, ensure excellent and consistent application materials. The new Henkel Technomelt MED Range includes a selection of seven adhesive grades designed to meet the requirements for different adult incontinence product applications.

Know-how & Expertise: Henkel supports customers with broad technical expertise and know-how during the transition with a program team that includes PS&RA, toxicology experts, supply chain and operations.

Selective Approach: Henkel's careful selection of raw materials, suppliers and production facilities ensures the absence of substances of concern and the highest standards of safety and formula control. This makes it possible to support manufacturers with standardized and comprehensive conformity declarations.

"As a leading supplier of adhesives to incontinence product manufacturers, we recognize that we take on a vital role in supporting our customers with reliable products designed with MDR compliance in mind, expert support, and with rigorous processes for transparency that offer confidence during the transition to medical device manufacturing," Eilyn Meneses Villabona concludes.

Additional information is available on [this website](#).

About Henkel

Henkel operates globally with a well-balanced and diversified portfolio. The company holds leading positions with its three business units in both industrial and consumer businesses thanks to strong brands, innovations and technologies. Henkel Adhesive Technologies is the global leader in the adhesives market – across all industry segments worldwide. In its Laundry & Home Care and Beauty Care businesses, Henkel holds leading positions in many markets and categories around the world. Founded in 1876, Henkel looks back on more than 140 years of success. In 2021, Henkel reported sales of more than 20 billion euros. The company employs about 53,000 people globally – a passionate and highly diverse team, united by a strong company culture, a common purpose, and shared values. As a recognized leader in sustainability, Henkel holds top positions in many international indices and rankings. Henkel's preferred shares are listed in the German stock index DAX. For more information, please visit www.henkel.com.

Photo material is available at www.henkel.com/press

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The following photo material is available:



Henkel is helping its customers ensure their products are ready for MDR. This is particularly important, as adhesives are key components of these products and highly relevant regarding this compliance.