

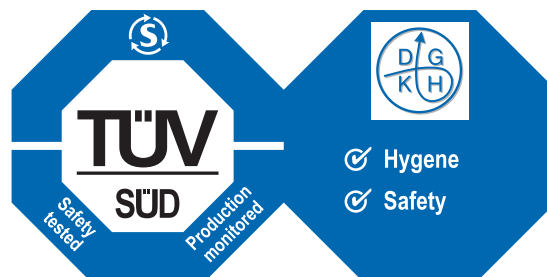
Cooperation for Hygiene – TÜV SÜD Product Service and the German Association for Hospital Hygiene Cooperate with Regards to the Hygiene Safety of Medical Devices

Safety for patients and the users of medical devices! To achieve this target, a main focus on hygienic aspects is required. TÜV SÜD Product Service, member of the TÜV Süd Group, together with the German Association for Hospital Hygiene (DGKH) combine their expertise by granting a combined test mark.

Since 1992, the technical committee “hygiene safety of medical technical devices and procedures” of the German Association for Hospital Hygiene (DGKH) has been evaluating the hygienic properties of medical devices at the specific request of manufacturers. The safety of devices is a focal point of the evaluation, taking into account the special conditions of use and the applied procedures as well as the current state of the art in science. Potential hazards through microbial contamination and chemical residuals are part of the evaluation as

well as limitations in the functionality due to unsuitable processing.

The committee, which is fully independent in their opinion-finding process, consists of experts from hospitals, science, and industry with theoretical and practical experience in hospital hygiene. It works in close contact with further sectors and working groups at the DGKH and other international organizations. The global target at DGKH is the complete quality management of hygiene in the medical practice and, derived from this, the ongoing assessment of potential infection risks arising from new medical devices, new techniques in diagnosis and therapy, new treatment strategies, and new processing methods. This assessment results in recommendations for users and specific test programs for the evaluation of the respective devices and processes.



www.tuev-sued.com/mhs

As a result of the cooperation between TÜV SÜD Product Service and the Technical Committee at DGKH, it is now possible to evaluate medical devices in the whole context. TÜV SÜD Product Service brings its knowledge and experience regarding safety, product, and production aspects and standards. DGKH adds hygienic aspects under the conditions of use and procedures in medical routine.

Who is this test mark of relevance to?

The test mark aims to document the suitability and safety of products and procedures from a hygiene perspective. With this test mark, the user can be sure that the practice implements hygienic products and/or procedures. The test mark is, however, by no means comparable to the CE mark – even though hygienic aspects are part of the essential requirements in the respective Medical Device Directives – as the requirements to be met for this test mark are far more detailed with regard to hygiene.

Additionally, the test mark can also be granted for other technical devices used in the hospital environment where hygiene forms an important aspect. The international validity of this test mark means that additional quality standards are being set for both European and non-European markets thereby contributing to the minimizing of risk for patients and employees within health institutions.

How can the dual test mark be attained?

Applications for the certificate and the test mark can be sent to TÜV SÜD Product Service or the Commission of the DGKH, together with complete documentation on the assembly, functioning, effectiveness, and the preparation procedure. Known risks, hazards, and contraindications in connection with the application of the product or procedure must be disclosed.

The documentation should contain:

- List of contents for the submitted documents
- Instructions for use
- Detailed description of the functional characteristics and process description including supporting documents
- Constructional drawing, circuit diagram, materials description, etc.
- Available examination reports, assessment, and test results
- Contraindications, potential risks, etc.
- Description of the quality assurance system in the manufacturing process and if relevant, a valid certificate

This documentation can be submitted in either German or English.

TÜV SÜD Product Service GmbH
Dr. Susanna Kerschl • Ridlerstr. 65 • D-80339 Munich
E-mail: susanna.kerschl@tuev-sued.de • Tel.: + 49 89/50 08 41 62
TÜV Product Service Ltd • Octagon House • Concorde Way
Segensworth North • Fareham • Hampshire • PO15 5RL
Phone: +44 (0) 1489 558100 • Email: info@tuvps.co.uk
Or you can visit us at: www.tuev-sued.com/mhs