HOHENSTEIN
MEDICAL

HOHENSTEIN MEDICAL
SERVICE PORTFOLIO

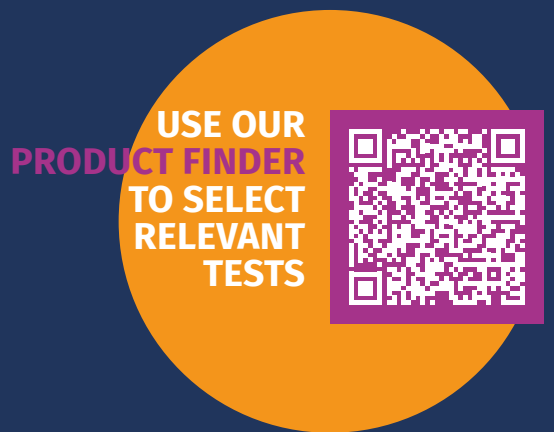
TESTING OF
MEDICAL DEVICES

The EU's Medical Device Regulation (MDR), which came into place on 26 May 2021, has reorganised the approval and monitoring of medical devices.
It aims to increase patient safety and improve transparency within the industry.
The MDR introduces stricter controls for manufacturers and expands the requirements for technical documentation and clinical evaluation.

For manufacturers, retailers and distributors of medical devices, this means that their processes must be adapted and new obligations must be met in order to ensure compliance with the regulation.

The **BIOCOMPATIBILITY** of medical devices is crucial to ensure that they are compatible with the human body.

The basis for the biological assessment of medical devices is the DIN EN ISO 10993 series of standards. With our product finder, you can quickly and easily find out which endpoints you must consider in the biological risk assessment of your product.



A special case is the biological assessment of gas pathways in medical devices, which is covered by the DIN EN ISO 18562 series of standards.

OUR OFFER

- **Chemical characterisation (according to DIN EN ISO 10993-18):**
  The analysis covers leachable and extractable substances from medical devices.

- **Cytotoxicity (according to DIN EN ISO 10993-5):**
  Tests cell-damaging substances.

- **Sensitisation (according to DIN EN ISO 10993-10, Annex C):**
  Tests whether a product has the potential to initiate an allergic reaction in the patient.
  Several key events are analysed.
  - ***DPRA:*** in-chemico test for the detection of covalent protein binding.
  - ***IL-18 RhE:*** Determines the activation of epidermal keratinocytes.
  - ***U-SENS:*** Detects the activation of epidermal dendritic cells.

- **Skin irritation (according to DIN EN ISO 10993-23):**
  Uses three-dimensional human skin models (reconstructed epidermis).

- **Test for irritation / mucous membrane damage (HET-CAM according to DB-ALM Method Summary n° 96):**
  Records reactions on the chorionallantoic membrane of chicken eggs as a model of the mucous membrane.

- **Biocompatibility of breathing gas pathways (according to DIN EN ISO 18562):**
  Alternative for the biological assessment of gas pathways of a medical device and its parts or accessories intended for ventilation or the supply of substances via the respiratory tract of a patient.

HOHENSTEIN OFFERS ANIMAL-FREE TESTING ACCORDING TO REGOCNIZED IN-VITRO METHODES

Revisions of various parts of the international ISO 10993 series of standards clearly show that the reduction and the elimination of animal testing should be aimed for.

In-vitro methods offer several advantages for testing the biocompatibility of medical devices:

1. **Animal-free:** in-vitro methods do not require animal testing. Instead, cell cultures or human tissue models are used, which is ethically and practically advantageous.
2. **Precise and reproducible:** In-vitro tests provide precise and reproducible results. Controlling the test conditions enables accurate analysis.
3. **Time and cost savings:** Compared to animal testing, in-vitro tests are faster and less expensive. This accelerates product development and approval.
4. **Specific endpoints:** in-vitro methods enable the targeted investigation of specific biological endpoints, e.g. cytotoxicity or skin irritation.

The **recognition of in-vitro methods** depends on the respective authority and the specific regulations. It is important to consider the requirements of the respective countries to ensure successful authorisation of medical devices.

WE PROVIDE YOU WITH NEUTRAL PROOF OF **EFFICACY** AND **SAFETY** OF YOUR **PRODUCT**

When used correctly, your medical device must not pose any avoidable risks to patients, users or third parties. As the manufacturer or authorised representative, you are responsible for this.

Medical devices must therefore fulfil other product-specific performance requirements in addition to biocompatibility. We support you in testing performance requirements in accordance with international standards or your individual specifications. This allows you to demonstrate the suitability of your product for its intended purpose.

CLEANLINESS OF THE **PRODUCTS**

WE TEST FOR YOU:

- **Microbiological cleanliness of the product** (bioburden)
- **Detection of bacterial endotoxins**
- **Surface analyses SEM/EDX**
- **Hygiene monitoring in the production environment and in cleanrooms**
- **Reprocessing in standardised procedures**
- **Influence of utilisation cycles and material ageing**

BARRIERE FUNCTION AND **PROTECTIVE** EQUIPMENT

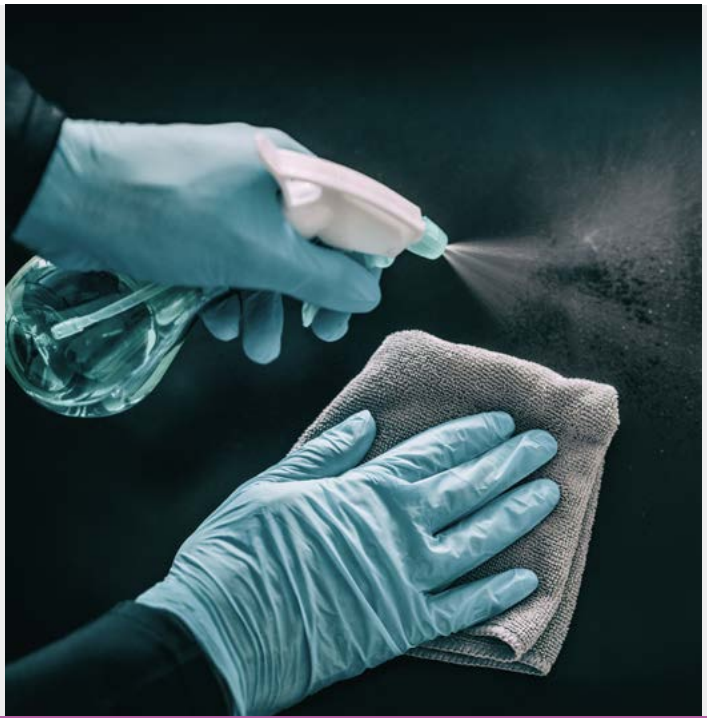
PHYSICAL AND MICROBIOLOGICAL PARAMETERS:

- **Requirement tests according to DIN EN 13795 for surgical textiles**
- **Requirement tests in accordance with DIN EN 14126 for protective clothing against infectious agents**
- **Requirements testing for protective gloves in accordance with DIN EN 374**
- **Requirements testing for medical face masks in accordance with DIN EN 14683 or FFP masks according to DIN EN 149**
- **Microbial ranking of porous packaging materials according to ASTM F 1608**

EFFICACY OF **DISINFECTANTS**

USE OUR PRODUCT FINDER TO SELECT RELEVANT EFFICACY TESTS

We offer **validations of product claims** in accordance with DIN EN 14885 and prepare **expert reports** for the listing of your formulations and procedures for surface disinfection, instrument disinfection and textile disinfection.
Whether bactericidal, yeasticidal, fungicidal, mycobactericidal, tuberculocidal or virucidal - the efficacy of your product must be proven both in the quantitative **suspension test** (Phase 2/Step 1) and in the **practical germ carrier test** (Phase 2/Step 2).



APPLICATION IN THE MEDICAL AREA

Phase 2/Step 1: - DIN EN 13727, DIN EN 13624, DIN EN 14348, VAH 8 and 9

Phase 2/Step 2: - Surface disinfection DIN EN 17387, DIN EN 16615, VAH 14.1 and 14.2
- Instrument disinfection DIN EN 14561, DIN EN 14562, VAH 15
- Laundry disinfection DIN EN 16616, VAH 17.1 and 17.2

APPLICATION IN THE VETERINARY AREA

Phase 2/Step 1: - DIN EN 1656, DIN EN 1657

Phase 2/Step 2: - Surface disinfection DIN EN 14349, DIN EN 16428

APPLICATION IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS

Phase 2/Step 1: - DIN EN 1276, DIN EN 1650

Phase 2/Step 2: - Surface disinfection DIN EN 13697
- Laundry disinfection DIN EN 17658

TESTING OPTIONS FOR **MEDICAL COMPRESSION TEXTILES, BANDAGES** AND **ORTHOSES**

- **Biocompatibility** (new/after material ageing or usage simulation)
- **Compression effect** (pressure curve, stretchability and elasticity)
- **Microclimate and wearing comfort**
- **Sizing and fit**
- **Wash resistance, functional retention after cleaning/ service life**
- **Colour fastness**
- **Seam strength**
- **Odour management**
- **Antimicrobial properties**

TESTING OPTIONS FOR **MEDICAL DEVICES** ON **INTACT SKIN**

(MEASURING DEVICES AND MEDICAL WEARABLES)

- **Chemical characterisation according to DIN EN ISO 10993-18**
- **Cytotoxicity according to DIN EN ISO 10993-5**
- **In-vitro sensitisation according to DIN EN ISO 10993-10, Annex C**
- **Irritation test according to DIN EN ISO 10993-23**
- **Microclimate and skin sensory properties**
- **Thermal insulation and cooling function**
- **Size data, 3D scanning**

TEST OPTIONS FOR **VENTILATORS** AND **INHALATION DEVICES**

DIN EN ISO 18562 applies to medical devices that have gas-mediated contact with the respiratory tract. It defines tests for the emission of particles and volatile substances from the gas pathways of such products as well as the assessment of leachable substances.

Assessment of the biocompatibility of the breathing gas pathways in medical applications

- **DIN EN ISO 18562-1 Evaluation and testing within a risk management process**
- **DIN EN ISO 18562-2 Tests for emissions of particulate matter**
- **DIN EN ISO 18562-3 Tests for emissions of volatile organic substances (VOCs)**
- **DIN EN ISO 18562-4 Tests for leachables in condensate**

THERAPEUTIC MEDICAL DEVICES

- **Ventilators**
- **Monitoring devices for respiratory gases**
- **Anaesthesia workstations**
- **Incubators**

TREATMENT OF GASES

- **Nebulisers**
- **Humidifiers**
- **Filters for ventilators**
- **Oxygen concentrators**

TRANSMISSION OF GASES

- **Ventilation tubes**
- **Masks**
- **Y-pieces**

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