



BBF STERILISATIONSSERVICE GMBH



steriXpert - Experts in all aspects of
Sterilisation, Microbiology...



... and Sterile
Packaging

**"One-stop"
Service**

steriXpert

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BBF STERILISATIONSSERVICE GMBH

is a young enterprise. It is, however, based on several decades of combined experience in the fields of sterilisation and microbiology.

The company has its beginnings in the Gamma Sterilisation Department which was set up in 1969 by Willy Rüschi AG. In 2002 the departments of Gamma Sterilisation and Microbiology were disincorporated and combined to form the new Rüschi Sterilisation Service GmbH (Ltd.).

In 2005 the present company was bought out by its present Managing Directors: Dr. Hermann Benedikter, Dr. Mario Bernkopf and Dr. Heinz Fischer and renamed BBF STERILISATIONSSERVICE GMBH.

Together the Managing Directors of BBF have over 50 years experience in the fields of Gamma Sterilisation, Microbiology, and in the Pharmaceutical and Medical Device Industries.

BBF Sterilisationsservice GmbH has – within its short life – become a leading contractor of gamma sterilisation and microbiological testing of medical products, pharmaceuticals and cosmetics.

Our integrated service spectrum, sterilisation and microbiology, is enhanced through new services in the areas of cleaning, assembly and packaging of medical devices.

steriXpert:

- You receive the following from one source:
Cleaning – Assembly – Packaging – Sterilisation
– Validation and microbiological testing
- The satisfaction of our customers is our priority.



Microbiology



Our microbiological laboratory offers you competence and experience.

From product development through production monitoring to final control: Profit from our know-how both in-house and on location in your company.

We are a competent partner in all questions regarding sterilisation safety, microbiological product quality and production hygiene. In addition we supply you with competent answers regarding biocompatibility.

The following is our extensive service spectrum:

- **Sterilisation Validation**
(e.g. dose setting, dose substantiation, dose auditing)
- **Microbiological Testing**
(e.g. bioburden testing, sterility testing)
- **GMP-conforming Hygiene Monitoring**
(e.g. air-borne particles and microorganisms)
- **Cleaning Validation**
(e.g. effectiveness of microorganism removal; reworking of medical devices; chemical and particular residues – via cooperating partner laboratories)
- **Biocompatibility**
(e.g. cytotoxicity, pyrogens/ endotoxins)

We work according to the following standards:
ISO 11137-2 • ISO 11737-1, -2

In addition we apply, on a case-by-case basis, all other standards which may be relevant to our testing and the services we offer.



Sterilisation / Gamma Irradiation

The use of gamma irradiation for the sterilisation of pharmaceuticals and medical devices is explicitly recommended by the World Health Organisation (WHO). Our experience in this area goes back to 1969 when the company was founded. Our facilities are subjected to regular audits by the U.S. FDA. We hold a pharmaceutical manufacturing license according to § 13 AMG (German Drug Law) for the irradiation of pharmaceuticals and are an accredited Foreign Manufacturer with the Japanese Ministry of Health.



Advantages of Gamma Sterilisation:

- Penetrating, safe and free of residue
- Sterilisation in the final package (i.e. no further packaging steps after sterilisation)
- Suitable for temperature sensitive products (frozen products can also be sterilised)
- Short cycle times (as a rule only 2–3 days between receipt and shipping of goods)
- "Overnight Service" available by agreement
- No quarantine or storage time necessary after sterilisation (immediate availability of product after sterilisation)
- No residues
- Parametric release of product on the basis of the irradiation certificate instead of time-consuming sterility testing or other release procedures (after validation of the sterilisation cycle)
- Integration of the sterilisation cycle in your logistics chain (i.e. we deliver sterilised products directly to your customers)

A Few Examples of Application:

- Disposable medical devices
- Implants
- Pharmaceuticals
- Pharmaceutical primary products
- Clean room materials
- Laboratory articles
- Packaging components
- Cosmetics and toiletries
- Food packaging
- Archive materials
- Animal skins and Trophies
- Shrink tubing
- Automobile industry
- Aeronautical industry

BBF employs a modern tote irradiation facility with a small dose window. In comparison to conventional palette facilities this method is especially suitable for the sterilisation of radiation sensitive products! We welcome your questions on this subject and will provide you with expert advice.



Sterile Packaging



The service of our packaging department is based on years of experience gained in the testing of diverse packaging systems.

We are able to provide the type of packaging you request, be it peel bags or blister packs, vacuum packaging or packaging under protective atmosphere.

We offer you competent advice and service in all aspects and phases of the packaging process, e.g. in

- Choice of packaging material
- Development and determination of packaging design
- Cleaning of products before packaging
- Subsequent assembly of product and packaging components
- Packaging of product
- Label design and labelling of product
- At BBF you will find competent partners for all phases and aspects of product packaging

At BBF packaging is performed in clean rooms of ISO Classes 7 and 8 (if necessary upgradable to Class 5). These clean rooms guarantee that the product is packaged under flawlessly hygienical conditions as a basis for a valid and successful sterilisation process. Both the environment and the cleaning and packaging processes are expertly controlled by our microbiological laboratory.

Of course, we will also sterilise the products which are packaged at our facility.

Products which are not suitable for gamma sterilisation may be sterilised with ethylene oxide in our ISO 13485 certified partner company. Other methods of sterilisation are made available on request.



Testing and Validation

The priority of the services offered by our packaging laboratory is proof of package integrity and maintenance of sterility by the sterile packaging over the duration of shelf life.

Sterile packaging of medical devices is expected to maintain the sterility of the contents up to its point and time of use, and throughout its shelf life. In addition to the microbiological barrier characteristics of the packaging components themselves, the tightness of the closures and seals are of crucial significance.

With respect to shelf-lives of up to five years or more it is of great importance to be able to predict that the microbiological barriers will remain undamaged up to the end of the shelf life.

Through accelerated stability studies and packaging tests on the basis the standards:

- DIN EN ISO 11607-1 und
- DIN EN ISO 11607-2

We are able to offer you expert support in these areas.

Take advantage of our services which include:

- Accelerated stability
- Seal integrity testing
(seal strength testing, burst testing)



- Leak testing
(seal tightness)



- Transport validation
(performed by our partner laboratory)



BBF Sterilisationsservice GmbH

In addition to our comprehensive services we also offer high-quality partial services like gamma sterilisation, microbiological testing or packaging.

Make use of our integrated service spectrum. All departments and services work closely together under one roof. This avoids the usual interfacing problems among different companies in these sensitive and safety-related areas.

As our customer, you receive expert and comprehensive advice in all matters related to cleaning, packaging, sterilisation, validation, microbiology and hygiene.

Since no transportation is necessary between the individual phases of product realisation, cycle times will be extremely short and you will save in transport and insurance costs.



We are certified according to:

- DIN EN ISO 9001
- DIN EN ISO 13485
- DIN EN ISO 11137-1, -2, -3



PUT US TO THE TEST.
WE LOOK FORWARD TO WORKING WITH YOU.

A few references and experiences

- Aesculap AG
- Dr. Mann Pharma
- Bayer Healthcare AG
- Coltène/Whaledent GmbH & Co. KG
- Friadent GmbH
- KLM Medizintechnik GmbH & Co. KG
- Nycomed Austria GmbH
- Paul Hartmann AG
- Smith & Nephew Orthopaedics GmbH
- Stryker Leibinger GmbH & Co. KG

You can find us at the following location:



BBF Sterilisationservice GmbH

Willy-Rüsch-Str. 10/1 • 71394 Kernen-Rommelshausen

Tel.: +49(0)7151. 94570-0

Fax: +49(0)7151. 94570-19

Email: bbf@steriXpert.de • <http://www.steriXpert.de>