

Radiation Sterilization

Product enhancement by irradiation



BGS

IDEEN **PLUS** ENERGIE



BGS: We optimize your products at three locations.

Radiation sterilization at BGS

What we do, we do with energy

In all areas of modern life people rely on products being free from pathogenic microorganisms. Sterility is essential not only in medical diagnostics and medical devices, but also in many of the production processes of modern industry – in the production of semiconductors, for instance. In biotechnology, food processing and the production of pharmaceuticals and cosmetics, sterile raw materials, equipment and packaging are indispensable.

Even under the best conditions of hygiene, the manufacture of a product, including its packaging, cannot result in a sterile state. As pioneers with more than 25 years' experience in the industrial use of beta and gamma radiation, BGS Beta Gamma Service takes the responsibility for this sensitive step – and is much in demand as a partner for industry. Using a method that is environmentally friendly, we destroy pathogenic microorganisms safely, fast, and reliably. We enjoy mastering new challenges. Over decades now BGS has optimized a wide variety of products, ranging from packaging materials and consumer goods to sensitive products such as endoprostheses and implants.

When optimizing your products by beta and gamma irradiation, you can rely on an innovative enterprise with certified quality. We will help you to enhance the value added of your products by providing services that are precisely tailored to your requirements.

BGS – your partner with many years' experience in the special treatment of sensitive goods

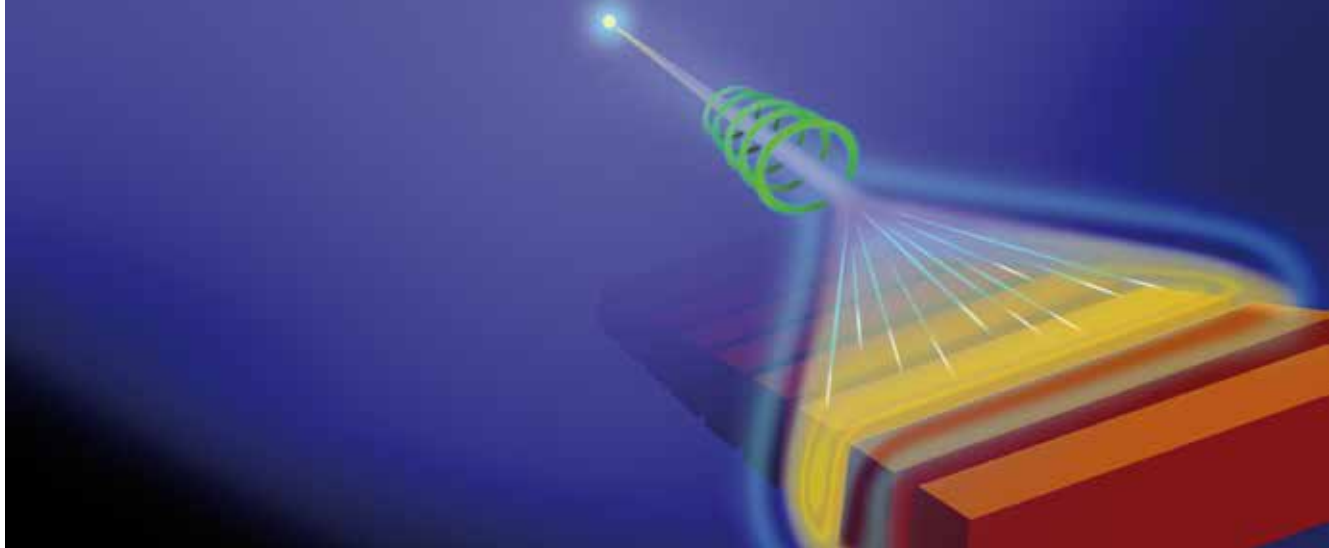
The comprehensive service of BGS expresses our wish to offer you a 'total care' package – whatever special tasks are involved:

- We integrate our services into your production process in a way which saves costs and resources: you send us your goods for irradiation, and they then go on from BGS to their final destination.
- We support you already at the development stage, to ensure that your products are ideally adapted for subsequent irradiation treatment.
- We cooperate with providers of special services, extending our service spectrum to include individual follow-on treatments and special logistic services.
- Our documented quality gives you certified safety.

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BGS as a partner in your process chain

Sterility 'made to order'

No question: when people buy a product, they expect safety. But this doesn't just apply to external characteristics or the product's functionality – it also covers the characteristics you can't see. Hygiene is the prime concern – for medical products, foods and body care products, as well as items which are part of everyday life, such as household goods and decorative articles.

The globalized trade processes of today bring their own particular challenges for consumer safety and hygiene. Only specialized service providers like BGS are in a position to treat goods effectively, so that they can be marketed safely. Thus BGS takes on a part of your responsibility towards customers and consumers – and integrates the treatment of your goods optimally into your production chain.

The radiation dose is determined by the initial microbial state of the product and the sterilization assurance. The whole production process, with radiation sterilization as the last step, has to be validated.



Highly effective, tailored irradiation: your advantages at a glance

- Sterilization by beta and gamma rays is a physical process, and therefore residue-free – unlike chemical sterilization methods.
- The products can be sterilized when already packed – together with their packaging.
- BGS fits seamlessly into your production or delivery process, minimizing costs and saving resources.
- The easy-to-use, environmentally friendly, product-friendly alternative to other processes such as gas or steam sterilization.
- Beta radiation is very fast – whole packaged units are sterile within seconds, and it takes just a few hours to process an entire truckload of products.

■ Medical devices

In medicine, the use of sterile products and medical disposables is a matter of course. Medical devices today are multifunctional and are manufactured from a very wide variety of materials. Despite their frequently complex geometrical structures, every part of them has to be sterile. The requirements for sterility are established by numerous standards, laws and regulations. In the bio-sciences and pharmacy, too, sterile materials and equipment are indispensable for research and processing.

Industrial sterilization processes in Germany are subject to the stringent requirements of the German law on medical devices ("Medizinproduktegesetz-MPG"). BGS holds the required certificates and licences and has many years' experience in dealing with international accreditation bodies and licensing authorities such as the US American Food and Drug Administration (FDA).

- Implants, prostheses
- Catheters, canulas, blood tubing systems
- Surgical drapes, instruments and examination gloves
- Dressings, suture materials, wound management systems, hydrogels
- Tubing systems, e.g. for infusion and respiratory therapy

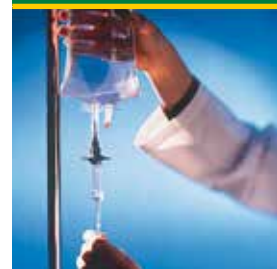
■ In vitro diagnostics and laboratory equipment

In vitro diagnostics occupy a special place in the field of medical devices. They do not come directly into contact with the patients, but are used, for instance, to analyse blood, tissue or urine. On no account must the results of these analyses be falsified by microorganisms contaminating the vessels. Thus sterility is absolutely essential for in vitro diagnostics. Here, too, BGS makes the decisive contribution to product safety.

- Blood sampling systems
- Vessels for urine samples, stool sampling tubes
- Petri dishes, microtiter plates, PCR trays, cell factories
- Pipettes and pipette tips
- Dosage systems
- Disposable syringes

■ Products for biotechnology, pharmacy and research

- Cell factories, handling and sampling equipment
- Container and dosage systems
- Packaging materials
- Raw materials
- Laboratory supplies
- Animal diets for research purposes
- Culture media
- Plant substrates





■ Packaging

With any form of packaging, there is the danger that the product will be contaminated by microbes. Radiation sterilization prevents the transfer of microorganisms from the packaging to contents such as cosmetics or liquid foodstuffs. At BGS, even the inner surfaces of closed packages can be reliably sterilized – a prerequisite for all products that need to be aseptically packaged and kept free from extraneous organisms.

Radiation sterilization is used for packaging and processing equipment made of metal and plastic, for the cosmetics and pharmaceutical industry, for food packaging and also in biotechnology.

In many sectors of industry, a sterile state is the prerequisite for reproducible, high-quality production results. BGS can contribute to enhancing the safety and reliability of your processing steps by the use of sterile raw materials, packaging and processing equipment.

- Bottles, tubes, jars and tins, lids
- Dosage systems and pump sprayers
- Bags, beakers
- Closures, caps and droppers
- Bag-in-box (bib) systems, inliners, flexitanks
- Protective clothing
- Fillers
- Pigments from mineral and vegetable sources
- Enzymes
- Preparations from vegetable and animal sources

Packages sterilized in this way are used, e.g. for:

- Fruit juice concentrates
- Fruit and vegetable juices
- Milk products
- Convenience foods
- Pharmaceuticals in solid and liquid form
- Cosmetics
- Pharmaceutical raw materials





Colourful, but contaminated: many pigments of natural origin cannot be used in their untreated state.

■ Raw materials

Without the colourful input from natural pigments, decorative cosmetics would be drab and dull. Natural pigments in their untreated state have a very high bioburden. All the more important to ensure that pigments of natural origin, which constitute a basic component of cosmetics, are safe and sterile.

By sterilizing the natural raw materials and their packaging, BGS makes an important contribution to production safety in the cosmetics industry.

Another positive effect of radiation sterilization is that after treatment the products keep for much longer, making preservatives unnecessary in some cases – an advantage both for the product and the user. For people processing the treated raw materials, there is no longer any health risk from exposure to aggressive pathogens.

In many other sectors, too, raw materials that are sterilized or have a reduced bioburden are used as a basis for a wide variety of products.

- Fillers and primary products for the cosmetics industry
- Pigments of vegetable and mineral origin
- Enzymes
- Humus
- Plant substrates
- Culture media
- Sand
- Herbal preparations and drugs
- Pollen
- Water



*Tinctures, powders:
BGS makes them sterile.*





■ Foods and animal feeds

Herbs and spices add the finishing touch to culinary creations. So that they can contribute taste without passing on unwelcome pathogens, they need to be pre-treated. Spices and herbs grown in natural surroundings contain large numbers of bacteria and moulds. Even a manufacturing process under hygienic conditions cannot prevent foods from being contaminated by microorganisms.

If steam sterilization is used, vitamin content and colour of the spices are badly affected and the aromatic substances, the 'soul' of the spice, are lost! When beta or gamma rays are used, the vitamins and flavours are preserved because the sterilization process takes place just above room temperature.

Animal feeds for pets and livestock are also regularly sent for treatment to BGS plants, to remove their bio-burden and prevent the transmission of pathogens. Packaged and deep-frozen products can also be reliably sterilized.

Treatment of foods at BGS...

- ... reduces losses from spoilage
- ... maintains production quality
- ... avoids food-borne diseases
- ... is safe and environmentally friendly

The World Health Organization WHO recommends sterilization by effective radiation. As early as 1992, the WHO stated that "the irradiation of foods does not cause any changes in the composition of the foods which create a toxicological risk to health."

Special irradiation of foods in Germany (BGS):

- Spices
- Grains
- Seeds

... and worldwide:

- Onions
- Dried vegetables
- Fish and seafood
- Nuts and pulses
- Fresh fruit
- Poultry
- Liquid egg

Every year 200,000 tonnes of foodstuffs, mainly spices, are irradiated worldwide to reduce their contamination with pathogenic germs.





■ Archival materials and documents

Files and other archives are not only rich in historic content: cellulose in the paper, traces on the paper from handling and glues in bindings all provide a rich nutrient base for moulds.

Mould spores can settle anywhere. If a document in the archive is infested, they may spread in a matter of hours under favourable conditions. If volumes, shelves of books or whole archives are attacked by dangerous moulds, it may be necessary to restore them at great expense, or even destroy them. When employees come into contact with archives contaminated by moulds, allergies or respiratory infections frequently develop. Thus not only do moulds attack objects – they are also a hazard for human health.

Gamma rays destroy obstinate moulds safely, fast and completely. The radiation dose is adjusted precisely to the type of paper and the application. Following treatment, the materials are totally radiation-free, and – unlike other processes involving e.g. the use of gases – do not emit any substances.

Gamma irradiation is the only method which enables complete archives to be decontaminated – including boxes and pallets – at a temperature not appreciably above room temperature. To provide you with a tailor-made solution against moulds, we cooperate with specialized service-providers who, for instance, collect the affected stock or perform manual dry cleaning after irradiation. This removes the dead moulds from each book page. Danger to health and re-infestation are then excluded, provided the archives are housed in a suitable atmospheric environment.

- Files
- Archives
- Analogue and digital data carriers
- Postal items with high safety requirements





■ Consumer goods

Toys have to stand up to a lot – so they need to be robust. Children are very sensitive to any health hazards – so toys need to be safe. This is not only a question of external properties: it is especially important for toys to be free of germs. Toys are frequently imported and may carry unwelcome “stow-aways” on board in the form of a wide variety of microbes and pathogens.

BGS is familiar with the different requirements of the materials and selects the type, duration and intensity of treatment accordingly. BGS also knows how sensitive the applications are, and always considers this responsible step from the viewpoint of the manufacturer. For several decades now, BGS has been sterilizing toys for manufacturers and importers.

Clothing and accessories, too, come to us from all over the world – and hygiene requirements are getting more stringent all the time. Often, these products only cease to pose a microbial threat after special treatment.

BGS destroys germs gently, fast and effectively by treating all possible products and objects from everyday life – a smart handbag, a new series of bodycare products, that chunky knife block for the kitchen, or the delicately-crafted candlesticks for the sitting-room shelf.

This gentle treatment of such a wide variety of articles leaves no traces in the treated objects. The highest degree of product safety is assured, without changing the characteristics of the product.

- Toys: balls, wooden toys, dolls, soft toys
- Textiles
- Leather goods
- Synthetics
- Household articles
- Decorative articles
- Bodycare products



■ Specialities and other applications

Antiques, too, are in good hands at BGS. Moulds and other harmful microorganisms can badly damage furniture and historic objects or, in the worst case, may destroy them beyond the point of restoration.

The irradiation process used by BGS is especially gentle. Unlike other methods it does not work with steam, which might inflict more damage on the surfaces, and there is no exposure to heat. Irradiation with beta and gamma rays takes place at room temperature and even the most delicate objects are reliably sterilized.

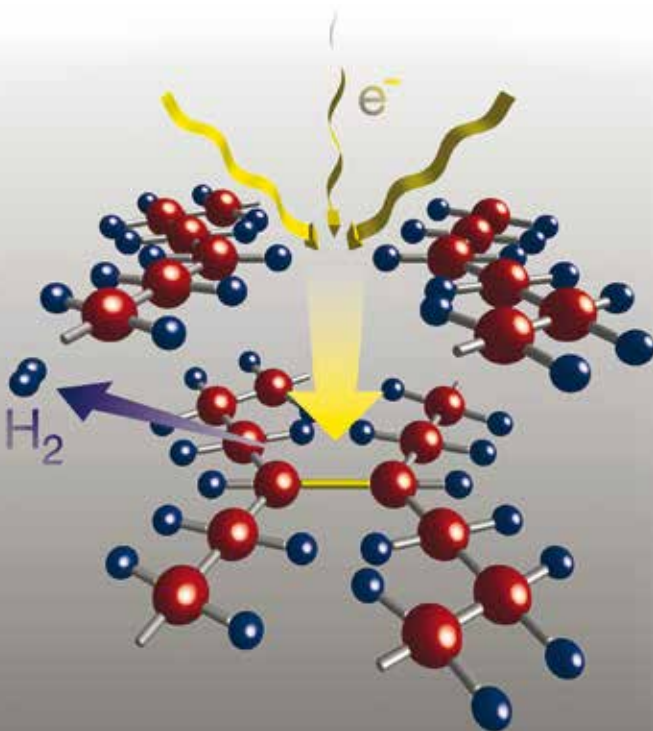
Even when plant culture and the treatment of seeds or seedlings is involved, BGS supplies the necessary care and expertise. Any microorganisms or other extraneous life forms which may harm the plants and cause substantial material damage are eliminated safely and gently by beta and gamma irradiation, without risk to the environment. The eco-friendly aspect of radiation sterilization is particularly apparent in comparison with conventional plant sterilization methods involving the use of gas.



Beta and gamma radiation: a short overview

Both beta and gamma rays are suitable for sterilization. The main difference between them lies in their depths of penetration and their dose rates:

- **Beta rays:** high dose rate and limited penetration depth
- **Gamma rays:** high penetration capability and relatively low dose rate



This is what happens in beta ray treatment

Electron accelerators can be compared to the construction of a cathode ray tube. A hot cathode emits electrons which are then accelerated in a strong electrical field, in a high vacuum. If energies greater than 5 MeV are required, BGS uses resonance accelerators of the Rhodotron[®] type. In these, electrons are accelerated in a cyclic alternating field in several stages, up to a maximum energy of 10 MeV. On leaving the accelerator, the electron beam is deflected so that it reaches the products to be irradiated as a fan-shaped beam.

This is what happens in gamma ray treatment

Opposite to beta treatment, during gamma irradiation whole pallets are passed directly to the conveyor system, which transports them individually into the gamma plant. Here, they are conveyed around the source rack which houses the radiation sources. The gamma rays result from the decay of the radioactive isotope Cobalt-60 (^{60}Co). The rays have a high penetration depth and can penetrate complete pallets or lots.

The process control system, which is precisely adjusted to take account of each individual product on the pallet, ensures that each pallet makes the predefined number of circuits. In this way, the total gamma irradiation dose that has been specified for each product is exactly applied.

Parameter	Electron beam	Gamma rays
Dose rate	high	low
Irradiation time	a few seconds	some hours
Energy source	electric current	Cobalt-60
Safety	can be turned off at any time	can be shielded at any time
Penetration depth	low	very high
Irradiation unit	individual boxes	pallets

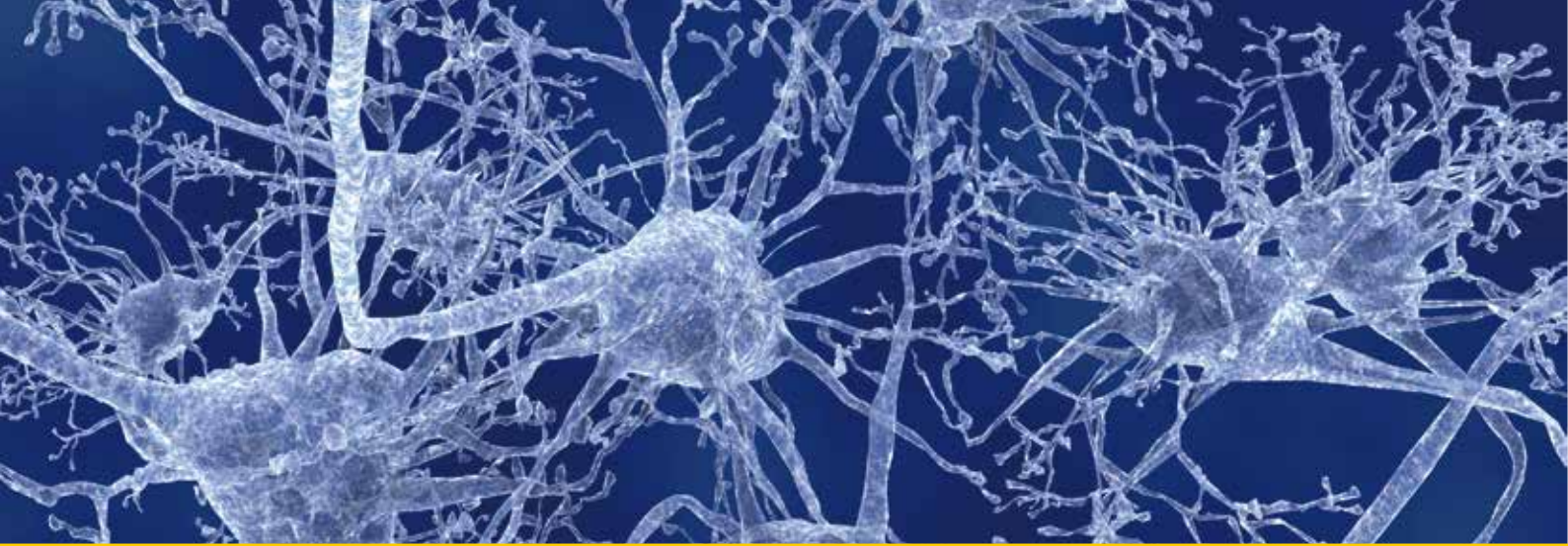
A reliable method: validation of radiation sterilization

Sterility means that a product is free from microorganisms capable of reproduction. The standard EN 556 defines a medical product as “sterile” if the probability of finding a viable microorganism in a product is smaller than 1:1,000,000. In technical manufacturing processes, this requirement can only be met up to a point. Here, BGS steps in as a reliable partner. As providers of special services with more than 25 years of expertise, we destroy the DNA of the microorganisms by radiation sterilization, thus inactivating them. Even closed packages are reliably sterilized by beta and gamma rays.

The process of radiation sterilization is regulated by DIN EN ISO 11137.

The gamma radiation source is completely shielded by a water basin more than eight metres deep.





Safety in three validation steps:

1. Microbiological validation

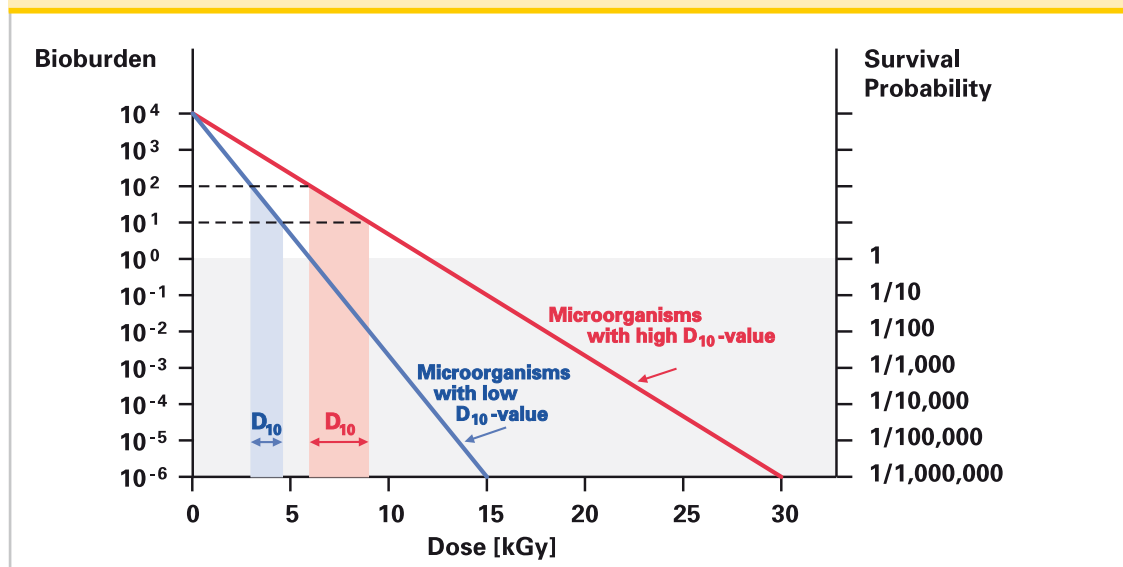
In microbiological validation, the radiation dose is established which will change a non-sterile product into a sterile one. To do this, the initial microbiological state, i.e. the numbers and types of microorganisms present, first has to be determined. Here BGS cooperates closely with accredited microbiological laboratories. Dependent on the bioburden and the resistance to ionizing radiation of the microorganisms found, an experimental verification has to be carried out to demonstrate that all products become sterile.

Various ways of experimental verification can be chosen.

Which way is the most appropriate depends on factors such as:

- Production conditions (degree of automation, production environment/clean room production/manual production)
- Selected materials (use of natural fibres such as cotton, or synthetics)
- Batch size and production quantities, continuous production, number of products

Effects of ionizing radiation on microorganisms



The different methods used for microbiological validation are described in:
DIN EN ISO 11137: Sterilization of health care products – Radiation,
Part 2 Establishing the sterilization dose.

A distinction is made between different methods of dose establishment:

Method 1: Dose setting using bioburden information

Method VD_{max} 15/25 : Confirmation of 15 kGy or 25 kGy as a sterilization dose

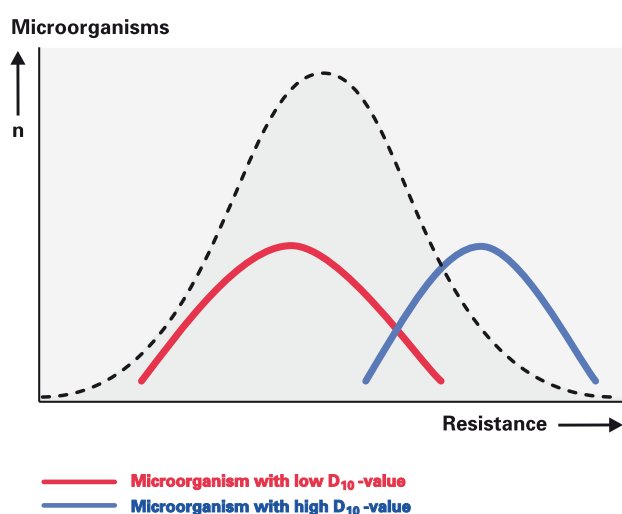
Method 2: Dose setting using incremental dosing

Method	No. of samples for bioburden determination	No. of samples for irradiation for VD/Sterility test	limits/ CFU values*
Method 1	3 x 10 items 10 / batch 3 batches	Table 5/11137-2 100 items from one batch SAL 10^{-2}	1-1,000,000
VD_{max} 25	3 x 10 items 10 / batch 3 batches	Table 9/11137-2 10 items from one batch SAL 10^{-1}	1-1,000
VD_{max} 15	3 x 10 items 10 / batch 3 batches	Table 10/11137-2 10 items from one batch SAL 10^{-1}	0.1-1.5
Procedure 2a			1-1,000,000
Procedure 2b			0.1-1.5

*CFU = Colony forming unit

Method 1: Dose setting using bioburden information

Normal distribution of resistances



The method depends on experimental examination of whether the response to radiation of bioburden is greater than that of a microbial population having a standard distribution of resistance (= SDR). In this method, the microbial contamination (bioburden) of the medical device is used as a basis for determining the sterilization dose. To determine this bioburden, ten samples are examined from each of three production batches.



When the 30 individual tests have been evaluated, an overall average bioburden is determined for all the batches. From this, a verification dose for SAL 10^{-2} can be determined according to Table 5 of DIN EN ISO 11137-2.

In the subsequent Verification Dose experiment, 100 individual samples are irradiated with the verification dose that has been determined. The actual dose delivered is not allowed to diverge from the verification dose by more than 10%. The 100 samples are then tested for sterility individually. The verification is accepted if there are no more than two positive tests of sterility from 100 tests performed.

Table 5 of EN ISO 11137-2 is used to obtain the sterilization dose for the product units using the closest value for the bioburden given in the table that is equal to or greater than the average bioburden for the product unit, and then reading off the dose necessary to achieve the desired SAL (sterility assurance level) of 10^{-6} . This value represents the minimum dose, which should not be fallen below because bioburden fluctuations may occur.

Excerpt from Table 5 of EN ISO 11137-2

Average bioburden	Sterility assurance level				
	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}
1.0	3.0	5.2	8.0	11.0	14.2
1.5	3.3	5.7	8.5	11.5	14.8
2.0	3.6	6.0	8.8	11.9	15.2
2.5	3.8	6.3	9.1	12.2	15.6
3.0	4.0	6.5	9.4	12.5	15.8
3.5	4.1	6.7	9.6	12.7	16.1
4.0	4.3	6.8	9.7	12.9	16.2
4.5	4.4	7.0	9.9	13.1	16.4
36	6.7	9.6	12.8	16.1	19.6
38	6.8	9.7	12.8	16.2	19.7
40	6.8	9.7	12.9	16.2	19.8
42	6.9	9.8	13.0	16.3	19.8

Average bioburden	Sterility assurance level				
	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}
110	8.1	11.1	14.3	17.8	21.3
120	8.2	11.2	14.5	17.9	21.5
130	8.3	11.3	14.6	18.0	21.6
140	8.4	11.4	14.7	18.1	21.7
150	8.5	11.5	14.8	18.2	21.8
160	8.5	11.6	14.9	18.3	21.9
170	8.6	11.7	15.0	18.4	22.0
180	8.7	11.8	15.1	18.5	22.1
1100	11.1	14.4	17.8	21.3	25.0
1150	11.2	14.4	17.8	21.4	25.1
1200	11.2	14.5	17.9	21.5	25.2
1250	11.3	14.5	18.0	21.5	25.2

Data in kGy

Safety in three validation steps:

2. Dosimetric validation

Dosimetric validation – determining dose distribution – ensures that the minimum dose fixed as a result of microbiological validation is adhered to in all areas, given specific packaging and a predetermined packing schema. To do this, the radiation conditions are fixed and the positions of the minimum and maximum doses absorbed by the packaged products are documented.

Basis:

- Specified product
- Specified packaging
- Specified arrangement of product inside the packaging
- Packing arrangement within the transport packaging (pallet / transport box)

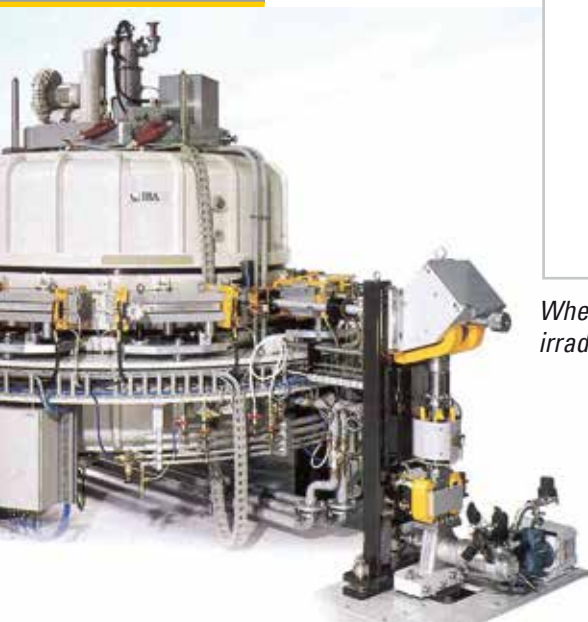
Determining dose distribution:

- Maximum dose positions (maxima)
- Minimum dose positions (minima)
- Positioning of the dosimeter in routine treatment in order to calculate the minimum and maximum dose

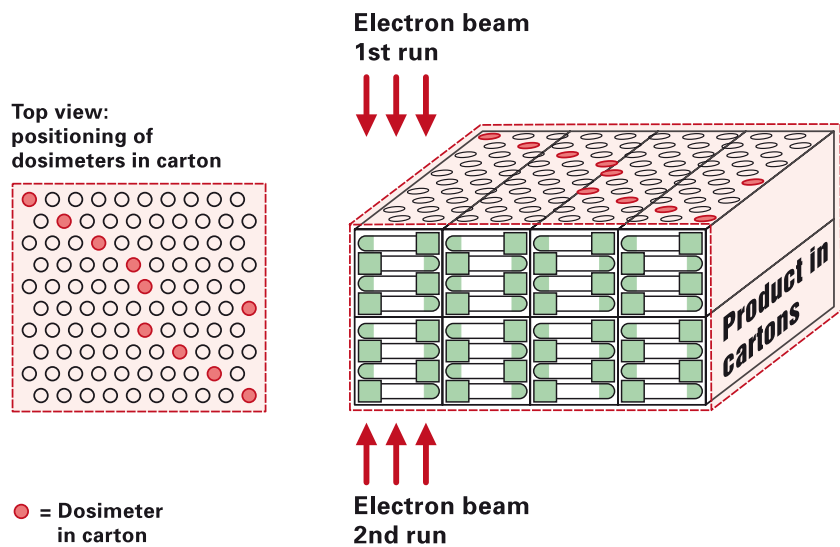


Dosimeters change colour. In this way, they give precise information about the radiation dose at a specific point.





Dosimetric validation, electron beam irradiation

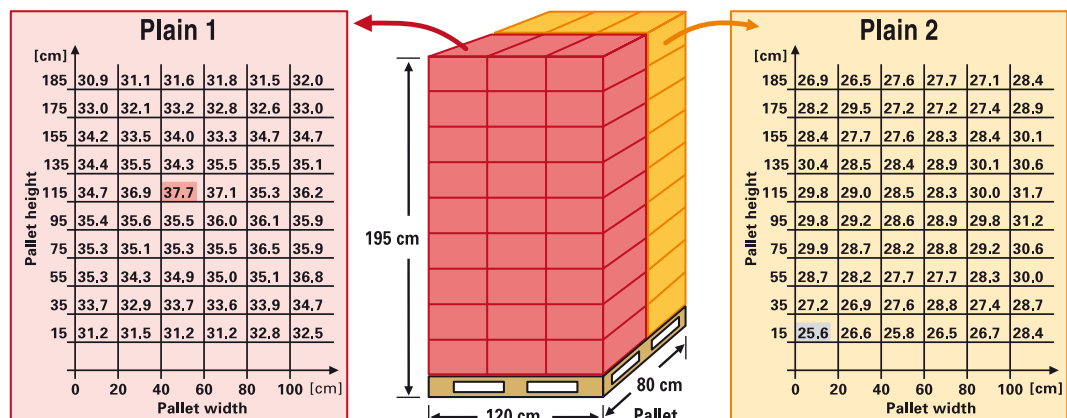


When irradiating products with accelerated electrons, a transport carton is the irradiation unit, therefore dose mapping is carried out on an individual carton.

Dosimetric validation, gamma plant

Irradiation in gamma plant
Dose distribution
Medical device
 (Min. dose 25 kGy)

Average density: $\rho = 0.17 \text{ g/cm}^3$
 Weight per unit area: $FG = 12.6 \text{ g/cm}^2$
 Maximum dose: $D_{\max} = 37.7 \text{ kGy}$
 Minimum dose: $D_{\min} = 25.6 \text{ kGy}$
 Max/Min ratio: 1.47



In the gamma facility we routinely irradiate Euro pallets. For this reason, the dosimetric validation of whole pallets with a defined maximum load is recommended.

Safety in three validation steps:

3. Application-related validation

The manufacturer verifies that the sterilized product, including the packaging material, fulfils the required property profile over the whole lifetime or shelf life. Since the product materials are decisive in determining whether radiation sterilization can be used, our experts will be pleased to advise you already at the product development stage.

As a result of dosimetric validation, the radiation conditions and the maximum acceptable dose are fixed.

Medical devices are often made wholly or partially from plastics. Already at the design stage, it is necessary to take into account possible changes in the properties of materials which may occur when they undergo sterilization following the production process. The sterile state that is achieved is preserved by suitable primary packaging. In application-related validation, possible changes to the medical device and its primary packaging are investigated under worst-case conditions (irradiation with maximum acceptable dose), bearing in mind that performance and properties of the product must be retained for the whole of the lifetime declared by the manufacturer. Depending on the type of product, various investigations are necessary.

Examples:

DIN EN ISO 11137:

Sterilization of health care products / Radiation
Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

- Sterilizing agent
- Determining the maximum acceptable dose
- Management responsibility
- Maintaining process effectiveness
- Process interruptions



Type of investigation	Duration of investigation
Accelerated ageing (simulated 2 years)	5-8 weeks
Seal integrity test	2 weeks
Real-time ageing	

The effects of radiation on material properties of plastics

Group	Polymer	Resistance	Remark
Thermoplastics	Aromatic polyamide-imides	***	High strength properties, resistant due to ring-shaped molecular structure.
	Polysulphone (PSU)	***	Inherent yellowish-brown colour. Highly resistant
	Polyimide (PI)	***	Highly resistant thanks to ring-shaped molecular structure.
	Polystyrene (PS)	**	Very resistant due to its ring-shaped molecular structure. Discolouration may occur in transparent grades. Impact-modified grades are less resistant.
	Acrylonitrile/butadiene/styrene (ABS)	**	The butadiene component begins to disintegrate upwards of approx. 100 kGy. Avoid high doses with impact-modified grades.
	Polycarbonate (PC)	**	Discolouration possible, special grades available. Discolouration may disappear after tempering.
	Aromatic polyesters (PET/PETG/PBT)	**	Very stable, retains its excellent transparency. Must be pre-dried prior to processing.
	Styrene acrylonitrile copolymers (SAN)	**	Yellowing from about 40 kGy possible.
	Polyvinylidene fluoride (PVDF)	**	
	Ethylene tetrafluoroethylene (ETFE)	**	
	Polyethylene (LDPE/HDPE/LLDPE/MDPE) and copolymers	**	Crosslinked for improved strength properties, hence reduced elongation at break. LDPE is the most resistant.
	Cyclic olefin copolymer (COC/COP)	**	Retains its high transparency and impact resistance.
	Polymethyl methacrylate (PMMA)	*	Discolouration at around 20-40 kGy.
	Cellulose acetate butyrate (CAB)	*	Retains its high transparency and impact resistance.
	Polyamides (PA) aliphatic and amorphous types	*	Discolouration possible. Avoid thin films and fibres. PA 11 and PA 12 give the best performance.
	Polyvinyl chloride (PVC)	*	Standard grades undergo changes, hydrochloric acid may be released. Strongly dependent on the formulation. Special grades are available for higher radiation resistance. Colour changes are possible.
	Polyvinylidene chloride (PVDC)	*	Yellowish discolouration, separation of hydrochloric acid.
	Fluorinated ethylene/propylene (FEP)	*	
	Polypropylene (PP) copolymer	*	More stable than PP homopolymers. Specially stabilized grades are recommended.
	Polypropylene (PP) homopolymer	*	Decline of mechanical properties with increase of radiation dose when stored. Only use stabilized types.
Thermosets	Polyacetal (POM)	o	Not recommended, very strong embrittlement.
	Polytetrafluoroethylene (PTFE)	o	Disintegrates very rapidly, releases corrosive gases. Avoid use.
	Phenol/formaldehyde (PF moulding compounds) Urea/formaldehyde (UF moulding compounds) Melamine/formaldehyde (MF moulding compounds) Unsaturated polyester resins (UP resins)	***	All thermosets have very high resistance. Some of them may release gaseous products.
Elastomers	Nitrile rubber	**	
	Ethylene propylene diene rubber (EPDM)	*	Crosslinkable grades are available. Resistance to radiation largely depending on formulation.
	Polyurethane rubber		
	TPU/TPE		
	Natural rubber	*	Property changes are very strongly dependent on wall thickness.
	Silicones	*	Increase in shore hardness is possible.
	Fluororubbers	*	
	Butyl rubber	*	Property changes occur already at low doses.

Referring to decline of mechanical characteristics:

*** highly recommended ** recommended * recommended with limitation o not recommended

Please note: This table can give only an indication. Behaviour against radiation may largely vary depending on molecular structure and additives used. In cases of doubt, please consult with our specialists.



*Cosmetic raw materials
and packaging are
also radiation sterilized.*

■ Material behaviour

Irradiation not only destroys microorganisms, it also changes material properties. These changes often depend on the radiation dose. From the results of the dosimetric validation, the dose range is obtained within which material changes need to be tested. Since mainly plastics are used, possible changes in material properties have to be taken into account already while the product is being developed.

The table on the left shows which polymers are suitable for the manufacture of products that are later going to be radiation sterilized. The radiation dose-ranges in the table are based on measurements of mechanical properties. Following radiation sterilization, application-specific tests are made in order to investigate which polymer is optimally suited to an individual application.

Depending on the sterility requirements, products are irradiated typically ranging from approx. 10 to 50 kGy. The dose range gives a first indication if a material is basically suitable for radiation sterilization. However, this overview cannot take the place of radiation testing of products within the necessary dose range.

*Sterilization is essential for the
safety of medical devices.*





Confirmation

DQS Medizinprodukte GmbH
 Hereby confirms that the company

BGS Beta-Gamma-Service GmbH & Co KG
 Fritz-Kotz-Strasse 16
 51674 Wiehl
 Germany

with the organizational units/sites as listed in the annex

fulfills, additionally to the certified **Quality Management System**, the requirements of

EN ISO 11137:2006

This confirmation is only valid in combination with the certificate 438339 MP29 (valid until 2016-04-28).

Effective Date	2011-04-29
Expiry Date	2016-04-28
Frankfurt am Main	2011-04-29


 Frank Gräichen
 Managing Director


 Stefan Hofmann
 Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

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Zertifikat



BGS Beta-Gamma-Service GmbH & Co KG
 Fritz-Kotz-Strasse 16
 51674 Wiehl
 Germany

Customer Name:
 Customer Address:

Customer no.: XXXXXXXX
 Date: 2013-XX-XX
 Page: 1 of 1

Certificate No.: XXXXXXXX
 BGS Order No.: XXXXXXXX
 Your order: XXXXXXXX
 Article: Medical Device
 LOT: XXXXXXXX

30 Cartons 1 Pallet

Type of irradiation:	Gamma
Min. dose (kGy):	25.00
Min. surface dose (kGy):	45.00
Irradiation date:	2013-XX-XX

Measured max. surface dose (kGy):	41.5
Determined minimum dose (kGy):	28.1

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CERTIFICATE



DQS GmbH
 Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company

BGS Beta-Gamma-Service GmbH & Co KG
 Fritz-Kotz-Strasse 16
 51674 Wiehl
 Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
 Irradiation with accelerated electrons or Gamma-rays as service for industrial products and medical devices for product dressing

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2008

Certificate registration no.	438339 QM08
Date of certification	2011-04-29
Valid until	2014-04-28


 Michael Drechsel
 Managing Director


 Jan Boge
 Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main

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CERTIFICATE



DQS Medizinprodukte GmbH
 hereby certifies that the company

BGS Beta-Gamma-Service GmbH & Co KG
 Fritz-Kotz-Strasse 16
 51674 Wiehl
 Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
 Treatment of medical devices with accelerated electrons or gamma-rays for sterilization

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2003 + AC : 2009

Certificate registration No.	438339 MP29
Certificate unique ID	170518913
Effective date	2011-04-29
Expiry date	2016-04-28
Frankfurt am Main	2011-04-29


 Frank Gräichen
 Managing Director


 Stefan Hofmann
 Head of Certification Body

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Certification

Since 1994, BGS Beta-Gamma-Service has maintained a certified Quality Management System which fulfills the requirements of EN ISO 9001 and EN ISO 13485. Complementing these certifications, we also meet the requirements of EN ISO 11137-1, 2, 3 relating to operators of radiation plants. Our Quality Manual is based on the following regulations concerning medical devices:

- **German law on medical devices**
(Medizinproduktegesetz – MPG)
- **Medical Device Directive 93/42/EEC**
- **EN 556-1 Sterilization of medical devices**
– Requirements for medical devices to be designated “Sterile”
- **EN ISO 11137 Sterilization of health care products – Radiation**
- **21 CFR 820 Quality System Regulation**
(USA/ FDA)
- **PAL/ MHLW Ordinance No. 169 (Japan)**

Imprint

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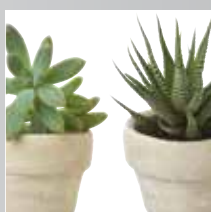
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17 right, 19 top

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21 down



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BGS

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