TS-QMA

Technical Specification:

Quality Assurance Requirements for the Delivery of Medical Devices and Medicinal Products to the Bundeswehr

BAAINBw ZtQ1.3
BUNDESWEHR

TS-QMA document history

Version	Remarks
2019-08-01	TS-QMA compiled
2019-08-08	Minor change to layout
2020-04-21	Incorporation of legal amendments
2020-05-07	Incorporation of Regulation (EU) 2020/561
2023-01-20	Incorporation of legal amendments
2025-03-10	Incorporation of legal changes and standards

Table of contents

Terms and definitions

The following sources apply for establishing terms and definitions:

- Regulation (EU) 2017/745
- Regulation (EU) 2017/746
- Medical Device Law Implementation Act, as amended
- EU Guide to Good Manufacturing Practice, as amended

Term	Definition
Government Quality Assurance	The process by which the appropriate national purchasing organisations (e.g. procurement agencies) establish confidence that the contractual requirements relating to quality are met.* In national (German) contracts, it is possible to reach an additional contractual agreement on government quality assurance in the form of quality inspection in accordance with Section 12 of the normally applicable General Terms and Conditions for Supply and Service Contracts – Part B (Verdingungsordnung für Leistungen – Teil B).
Customer	A government and/or NATO organisation that concludes with a contractor a contract laying down the product and quality requirements..
Contractor	An organisation (company) that acts in a contract as the provider of products to the customer.
BfArM	Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)
CAPACorrective and Preventive Action	
DMIDS	German Medical Devices Information and Database System (Deutsches Medizinprodukte-Informations- und Datenbanksystem)
GQAR	Government quality assurance representative (also quality controller, if applicable)
Good manufacturing practice (GMP)	Good manufacturing practice (GMP) is the part of quality assurance that ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use in accordance with the marketing authorisation, the authorisation for clinical trials and/or the product specification.
Good distribution practice (GDP)	Good distribution practice is the part of quality assurance that ensures that the quality of medicinal products is maintained throughout all stages of the supply chain, from the site of manufacture to the pharmacy or person authorised or entitled to supply medicinal products to the public.
IVDR	Regulation (EU) 2017/746
MDR	Regulation (EU) 2017/745
NATO	North Atlantic Treaty Organisation
PEI	Paul Ehrlich Institute (Federal Institute for Vaccines and Biomedicines)
Other products	Products that are not medical devices/accessories or medicinal products.

TS-QMA	Technical Specification: Quality Assurance Requirements for the Delivery of Medical Devices and Medicinal Products to the Bundeswehr
Sub-suppliers/Subcontractors	Subcontractors or sub-suppliers supply the contractor with products and/or services.
Administrative assistant	An external employee of the customer who provides assistance with government quality assurance.
ZLG	Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices

Scope

The Technical Specification for the Supply of Medical Devices and Medicinal Products to the Bundeswehr (TS-QMA) is a document that the Bundeswehr contractually agrees on with contractors/suppliers in addition to the relevant national and EU regulations when MDR/IVDR products, other products or pharmaceuticals are purchased. In addition, the TS-QMA also governs qualification requirements for contractors who carry out maintenance/repairs on MDR/IVDR products.

> Since health facilities do not only require MDR/IVDR products or pharmaceuticals, the product group of "other products" was included in the TS-QMA.
>
> Under certain circumstances, MDR/IVDR products, other products and pharmaceuticals can be procured/integrated as part of the performance of weapon system contracts. In these special cases, TS-QMA may be agreed on in addition to the usual contractually agreed quality assurance.

Bundeswehr contractors may pass this document on to suppliers as a contractual requirement.

Crisis situations

As a general rule, the Bundeswehr is subject to the legal requirements for procurement. In crisis situations, legal or other requirements can change very quickly. The contractor must take this into account in such cases.

Purpose

TS-QMA defines minimum quality requirements that, according to the customer (Bundeswehr), must be observed by economic operators, distributors or manufacturers throughout the entire supply chain. In addition, contractual agreements are made on rights of access, rights of inspection, and auditing rights of the customer’s representatives. The proper application of the requirements contained in this TS-QMA creates trust in the contractor’s ability to deliver products that meet the customer’s contractual requirements.

The spectrum of products covered by the TS-QMA comprises:

Products	Product type	Legal basis
MDR and IVDR products	Medical devices	MDR – Article 2
	Accessories for medical devices	MDR – Article 2
	System and procedure packs	MDR – Article 2
	Products listed in the groups of products without an intended medical purpose.	MDR – Annex 16
	In vitro diagnostic devices	IVDR – Article 2
	Accessories for *in vitro* diagnostic devices	IVDR – Article 2
	'Old' devices – and exclusively such devices – that may still be placed on the market on the basis of provisional regulations based on an 'old' conformity assessment procedure Devices that do not require a Notified Body must immediately comply with the MDR/IVDR. (Often class 1 devices)	MDR – Article 120 and Regulation (EU) 2024/1860 IVDR – Article 110 and Regulation (EU) 2022/112
Other products	Products that do not belong to the MDR/IVDR product types or medicinal product types.	-
Medicinal products	Medicinal products for human use	Medicinal Products Act
	Veterinary medicinal products	Regulation (EU) 2019/4, 2019/5, 2019/6 and Veterinary Medicinal Products Act
	Veterinary technical products	Veterinary Medicinal Products Act

Government quality assurance and quality control

The contracting authority generally waives performance of a quality control inspection unless it is stipulated in the contract.

However, all products are subject to the contractual right to government quality assurance. The customer may, to an appropriate extent, verify that the quality assurance requirements are met, e.g. by means of a meeting on the premises of the contractor or an audit.

The customer may only make use of this right if:

- they have received warranty claims or incident reports;

- the contractor has informed the responsible authorities (or the customer) about product risks;
- the CE marking was awarded on the basis of a type examination and, by way of exception, there is no quality management system in accordance with DIN EN ISO 13485;
- product samples have to be taken for quality control purposes and examination in Bundeswehr testing facilities;
- the customer/purchaser wishes to conduct a potential analysis or a supplier appraisal (requires mutual agreement);
- a special authorisation according to Section 90 of the Medical Device Law Implementation Act (Medizinprodukterecht-Durchführungsgesetz – MPDG) is to be carried out by the competent Bundeswehr agencies;
- representatives of the Bundeswehr as a customer wish to obtain product information on site;
- representatives of the Bundeswehr as a customer wish to present risk assessments from the customer's point of view on site;
- government quality assurance in the form of a quality inspection is a contractual requirement.

Rights of access and rights of support

The Bundeswehr agrees with the contractor the rights of access and rights of support defined here, even if they will rarely be used in practice. The customer’s representatives may wish to verify the contractual quality assurance on site, e.g. in the event of a supplier appraisal, government quality assurance, etc.

Customer representatives may be:

- Bundeswehr personnel, e.g. pharmacists, doctors, soldiers, project managers, purchasing officers, quality controllers/personnel of the Centre for Technical Quality Management,
- administrative assistants.

The customer must ensure that its representatives are professionally competent, including in matters of:

- evaluating processes in the field of quality assurance (not product assessment)
- technical assessments from the perspective of the customer/Bundeswehr as a client

No information that the customer receives from the contractor may be forwarded to third parties unless there are reporting channels to be observed, such as a duty to report to responsible authorities or, for example, to affected NATO countries if a government quality assurance process has been agreed on in the form of international quality control.

The contractor guarantees the following rights of access and support for the customer’s representatives:

1. right of access to all facilities in which the contractually agreed work is carried out;

2. provision of information relating to the fulfilment of the requirements specified in the contract;

3. unrestricted ability to check whether the requirements specified in the TS-QMA are being met;

4. unlimited scope to verify that the sub-supplier is meeting the requirements specified in the TS-QMA (the contractor will be notified before checks take place); The contractor will be informed before the evaluation takes place.

5. support for participation as an observer in order to evaluate from a customer perspective how the contractor or subcontractor assesses, verifies, validates, tests, inspects or releases products;

6. provision of office space with lockable doors;

7. access to information and communication facilities;

8. submission of contractor documents necessary to confirm that the product meets the contractual requirements;

9. issuing of contractor documents necessary to confirm that the product meets the contractual requirements;

10. access to inspect the risk management documents and the CAPA process;

11. access to inspect the Technical Documentation for Medical Devices.

Point of contact for customer representatives

Point of contact for quality assurance

The contractor's highest level of management appoints from the management organisation a management representative for government quality assurance matters, who, irrespective of their other tasks, must have the necessary organisational authority and freedom to solve quality issues. The management representative reports directly to the top level of management. In small companies, the managing director may assume this function.

Among other things, the management representative has the responsibility and the authority to ensure that the processes required for the quality management system are in place, implemented and maintained. This also includes cooperation with the GQAR and/or the customer on matters concerning quality. The management representative must have the appropriate competence with regard to Quality Management.

Customer's audit

If the customer is entitled to carry out government quality assurance inspections then the customer may, via representatives, also carry out supplier audits, i.e. client audits from the contractors' perspective. The audit can be made up of different kinds of audits to form an overall audit, e.g. a system audit, a process audit, a CAPA audit, etc. An audit may also be necessary in the event of a mutually requested supplier appraisal.

In each individual case, the customer and the contractor agree on how the audit is conducted.

Contractual quality assurance requirements

- MDR and IVDR products

- Other products

- Medicinal products, including accessories
- Legal Requirements

The following applies to MDR and IVDR products:

Note on legal requirements:

- EU law: Regulation (EU) 2017/745 in combination with Regulation (EU) 2023/607 and Regulation (EU) 2024/1860
- EU law: Regulation (EU) 2017/746 in combination with Regulation (EU) 2022/112 and Regulation (EU) 2024/1860
- In addition to Regulations (EU) 2017/745 and (EU) 2017/746, the German legislator has established specific national provisions in addition to EU law by adopting the Medical Device Law Implementation Act.

General requirements for distributors and manufacturers

- All MDR products and all IVDR products must bear a valid CE marking.
- If the manufacturer is located in a country where Regulations (EU) 2017/745 and (EU) 2017/746 do not apply, it must be verified that an authorised representative who is resident within the EU assumes legal responsibility.
- An EU declaration of conformity applicable to MDR and IVDR products is included with the delivery.
- As a rule, the declaration according to Regulation (EU) 2017/745 – Article 22 must be included in system and procedure packs.
- The economic operators concerned (not the distributors) must ensure that their obligations with regard to registration in the EUDAMED database are fulfilled. Transitional legal provisions can be observed. Distributors can use these databases for inspections within the scope of their distributor obligations (e.g. SRN number, Basic UDI-DI etc.).
- A legal unique device identifier (UDI) must be affixed to the medical device (or in vitro diagnostic device). Transitional legal provisions may be observed in this context.
- All legal quality assurance requirements must be fulfilled. MDCG documents of the Medical Device Coordination Group (MDCG) can be used as a guideline for interpretation of the requirements.
- If the installation/operation of medical devices has already been contractually agreed, the legal requirements of the Ordinance on Operators of Medical Devices must be observed, e.g. with regard to manufacturer's instructions on medical devices, entries in the medical devices log book, inventory as well as requirements concerning maintenance/metrological checks.

Quality assurance requirements for importers, authorised representatives

- The legal requirements apply.

Contractual quality assurance requirements for distributors

- Distributors must verify that an EU declaration of conformity is available for the medical device in question and that the device bears a CE marking.

- Distributors must verify that the manufacturers of medical devices have carried out quality assurance measures that at least comply with the TS-QMA requirements. Products for which no adequate quality assurance has been performed must not be delivered to the Bundeswehr.

- The storage and transport conditions for medical devices must comply with the manufacturer's requirements.

- For products with a limited shelf life, the distributor must check the expiry date. The remaining shelf life must be determined and communicated to the customer before delivery.

- Prior to delivery of medical devices, distributors must verify that the device in question is not subject to any risk information or product recalls. In addition to such information provided by the manufacturer, relevant information from the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute must also be taken into account. Devices subject to recalls or risk information must not be delivered to the Bundeswehr.

- Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available must immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. They must keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where applicable, the manufacturer's authorised representative and the importer informed of such monitoring and provide them with all relevant information upon request.

- Upon request by the customer, distributors must provide any information and documentation that is available to them and that is necessary to prove conformity of a device.

- Distributors must assess their suppliers/manufacturers in terms of quality. This assessment must be clearly reflected in the future selection of all procurement sources.

- If the distributor is aware that the purpose/use of the medical device as intended by the manufacturer is inconsistent with its actual use by the Bundeswehr, the distributor must notify the customer and initiate measures as necessary. Important note: Distributors, importers or other persons may be assigned manufacturer's obligations in accordance with Regulations (EU) 2017/745, Article 16 and (EU) 2017/746, Article 16.

Contractual quality assurance requirements for manufacturers

In principle, the Bundeswehr requires manufacturers of medical devices to have a quality management system according to DIN EN ISO 13485 in place and to apply it to medical devices of the Bundeswehr.

Legal requirements governing quality assurance and risk management must always be observed.

Manufacturers must monitor their products supplied to the Bundeswehr as far as possible. They must check compliance with the intended purpose. In some exceptional cases (which must be evident from the contract), medical devices are used in Bundeswehr aircraft, ships, tanks and tents under different global climatic conditions:

- vibrations, e.g. when installed in tanks;

- salt spray resistance when used in the Navy;

- altitude, e.g. when used in aircraft – at the risk of decreasing dielectric strength of electronic components.

- Military equipment (e.g. radio) may interfere with the functioning of medical devices.

With the participation of notified bodies, the contractor must initiate hardening measures as necessary to ensure safe operation – safety for patients, users and third parties. Once hardening measures are complete, the intended purpose of the device must be updated.

For class 1, 1* and 2a medical devices or in vitro diagnostic devices with low risk levels exceptions are permitted if the manufacturer performs a type examination as a prerequisite for CE marking. Minimum quality assurance requirements are listed in the table below. The Bundeswehr accepts quality management systems according to 21 CFR 820.

Minimum quality assurance requirements for manufacturers	
Medical devices	
Class 3 and 2b medical device, invasive	• DIN EN ISO 13485 • DIN EN ISO 14971 • DIN EN ISO 10993
Class 3 medical device and active medical devices	• DIN EN ISO 13485 • DIN EN ISO 14971
Class 2b medical device	• DIN EN ISO 13485
Class 2a, 1* and 1 medical device	As a minimum requirement: • DIN EN ISO 13485 In exceptional cases: • e.g. for small enterprises: CE marking based on type examination In exceptional cases, the customer will tolerate quality assurance based on legal requirements as a minimum. In such cases, the contractor must take quality assurance measures to ensure the safety of patients, users and third parties. Harmonised standards must be applied where appropriate from a regulatory perspective. The customer is entitled to visit the contractor's premises to observe how quality assurance measures are implemented.
In vitro diagnostic devices Important note: In accordance with Regulation (EU) 2017/746, new IVD medical device classes have been defined (A, B, C, D).	
In vitro diagnostic devices	• DIN EN ISO 13485 • In high risk cases: DIN EN ISO 13485 and DIN EN ISO 14971

In vitro diagnostic devices where a type examination was the basis of the CE marking	• In exceptional cases, the customer will tolerate quality assurance based on legal requirements as a minimum. The contractor must take quality assurance measures to ensure the safety of patients, users and third parties. Harmonised standards must be applied where appropriate from a regulatory perspective. The customer is entitled to visit the contractor's premises to observe how quality assurance measures are implemented.

Supplementary guidelines for the repair/maintenance of MDR/IVDR products

- The national provisions of the Ordinance on Operators of Medical Devices apply.
- Maintenance activities must be carried out in accordance with the manufacturer's specifications (MDR/IVDR product).
- The contractor must ensure that the personnel involved in maintenance/repair activities are competent and not bound by instructions.
- If required, the contractor will provide support in making entries in the medical devices log book (e.g. if the contractor has to carry out metrological checks or technical safety checks on the basis of contractual arrangements).

Excerpt from Section 5 of the Ordinance on Operators of Medical Devices: If specific requirements have to be met for carrying out a job IAW this Ordinance (Note on the application of Section 5: Section 7 No 2 of the Ordinance on Operators of Medical Devices lays down that) the work in question may only be performed by individuals who

1. have current knowledge regarding the respective job as a result of having undergone suitable training and due to relevant professional experience,
2. with respect to their expert assessment, are not bound by instructions and
3. have the means at their disposal that are needed to perform the respective job properly and plausibly – especially rooms, equipment and other tools such as adequate measuring and testing equipment/facilities.

The following applies to other products:

General requirements for distributors and manufacturers

- Customer's requirements must be identified, fulfilled and documented by the contractor.
- If required by EU legal norms (e.g. EU PPE Regulation), other products must bear a valid CE marking and be accompanied by an EU/EC declaration of conformity or EU/EC certificate of conformity (type examination) for each applicable EU legal rule. Additionally, distributors must check EU/EC declarations of conformity and EU certificates of conformity for correctness.
- All legal quality assurance requirements must be fulfilled. This also applies to "good laboratory practice", if required by law (e.g. Biocidal Products Regulation, Chemicals Act, etc.)
- Quality assurance must at least meet the requirements of DIN EN ISO 9001 (or DIN EN 9120 as an additional option for distributors).

- Other products must be delivered in an appropriate clean condition.
- Contractors must agree with suppliers on quality assurance commensurate with the risk involved.
- Storage and transport conditions must at least comply with the manufacturer's requirements where such requirements exist.
- All other products must be permanently marked at the manufacturing site, on the other product itself or, in exceptional cases, only on the packaging in order to ensure identifiability/traceability throughout the entire supply chain. The marking must reflect the configuration status of the other product in question.
- Contractors must keep a list of all incoming complaints and select suppliers only on the basis of past positive experience/quality capabilities.
- Other products with quality deficiencies must not be delivered to the Bundeswehr.

Quality assurance requirements for importers, authorised representatives

- The legal requirements apply.

The following applies to medicinal products (including veterinary medicinal products)

General requirements:

- Only approved medicinal products may be distributed.
- Legal requirements must be observed, including:
  - Medicinal Products Act and Ordinances relating to the Medicinal Products Act
  - Regulations (EU) 2019/4, 2019/5 and 2019/6, Veterinary Medicinal Products Act, TAMKatV (Ordinance on the categorisation of veterinary medicinal products) "Good Distribution Practice" according to EC Guideline 2013/C 343/01
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Special case: Requirements for veterinary products

- Section 2 of TAMKatV (Ordinance on the categorisation of veterinary medicinal products) sets out rules for over-the-counter veterinary medicinal products and veterinary technical products (VMTPs).
- In the manufacture and trade of VMTPs, minimum quality assurance requirements IAW DIN EN ISO 9001 apply. Animal welfare must be observed. Veterinary treatment must not result in endangering animals, users of VMTPs and third parties.
- Distributors must purchase VMTPs from a safe source of supply and have to conduct an extended incoming and outgoing goods inspection which is to ensure that the use of the VMTPs does not entail a risk for animals, users of the VMTPs and third parties.

Requirements for distributors (medicinal products for human and/or veterinary use):

- Distributors are subject to the requirements of "Good Distribution Practice" according to EC Guideline 2013/C 343/01.
- In their contracts with suppliers, distributors must ensure:

1. That subcontractors and subsuppliers implement the requirements of the EU GMP Guide and ensure that this requirement is forwarded to the production plant. This also applies to countries outside the EU.
2. That distributors can, upon request, inspect the manufacturing site to verify proper implementation of all legal requirements.

- Distributors must also ensure legal reporting channels throughout the entire supply chain.

Requirements for manufacturers (medicinal products for human and/or veterinary use):

- Manufacturers must operate and further develop a pharmaceutical quality management system within the company.
- Good manufacturing practice (GMP) is the part of quality assurance that ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use in accordance with the marketing authorisation, the authorisation for clinical trials and/or the product specification. Manufacturers must ensure this and apply the EU GMP Guide required by law.
- Legal requirements must be observed (e.g. Medicinal Products Act, Ordinances relating to the Medicinal Products Act).

Reporting obligations of contractors

- Contractors must report to the competent authorities all serious incidents and safety-related corrective action associated with medical devices, including accessories/in vitro diagnostic devices, including accessories.
- For medicinal products for human and veterinary use, legal reporting channels must be ensured by contractors.

Additionally, the customer may be notified by email to the address below if considered necessary in view of the risk involved.

AMMPSicherheit@Bundeswehr.org

Standards and laws/regulations

Index		
Standard	Title	Version
2013/C 343/01	Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use; these Guidelines are based on Article 84 and Article 85b(3) of Directive 2001/83/EC and Directive 2011/62/EU.	5 November 2013
AMWHV	Ordinance on the Manufacture of Medicinal Products and Active Agents/Note: contains a binding requirement for the EU GMP Guide	Latest version

Index		
Standard	Title	Version
Medicinal Products Act, including related ordinances	German national Act on Marketing Medicinal Products (Medicinal Products Act)	Latest version
ChemG	Act on Protection against Hazardous Substances (Chemicals Act) (*Gesetz zum Schutz vor gefährlichen Stoffen (Chemikaliengesetz – ChemG*))	Latest version
ChemVwV-GLP	General administrative regulation on the procedure of government supervision of compliance with the principles of good laboratory practice (*Allgemeine Verwaltungsvorschrift zum Verfahren der behördlichen Überwachung der Einhaltung der Grundsätze der Guten Laborpraxis* – ChemVwV-GLP)	Latest version
DIN EN ISO 10993	Biological evaluation of medical devices (Part 1 - Part xx)/Note: The biological safety of medical devices must be evaluated and ensured on the basis of the DIN EN ISO 10933 series of standards.	Latest version
DIN EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	Latest version
DIN EN ISO 14971	Medical devices – Application of risk management to medical devices	Latest version
DIN EN ISO 18562 Part 1, Part 2, Part 3 and Part 4	Biocompatibility evaluation of breathing gas pathways in healthcare applications	Latest version
DIN EN ISO 20417	Medical devices – Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12); German version EN ISO 20417:2021	Latest version
DIN EN ISO 60601-1-12	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	Latest version

Index		
Standard	Title	Version
DIN EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	Latest version
DIN EN 62353 (VDE 0751-1)	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment	Latest version
DIN EN ISO 9001	Quality management systems – Requirements	Latest version
DIN EN ISO 9120	Quality Management Systems - Requirements for Aviation, Space and Defence Distributors	Latest version
EU Guide to Good Manufacturing Practice (GMP)	Rules governing medicinal products in the European Union: EU Guidelines on Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use	Latest version
IPC/WHMA-A-620	Requirements and Acceptance for Cable and Wire Harness Assemblies (Class 3)	Latest version
EU Medical Devices Adaptation Act (as soon as in force)	German national act adapting current medical devices legislation to Regulation (EU) 2017/745 and Regulation (EU) 2017/746	Latest version
MPBetreibV	German national ordinance on the installation, operation and use of medical devices (Ordinance on Operators of Medical Devices -*Medizinprodukte-Betreiberverordnung* – MPBetreibV)	Latest version
MPDG	Act to Implement EU Regulations Concerning Medical Devices (Medical Device Law Implementation Act (*Medizinprodukterecht-Durchführungsgesetz* – MPDG))	Latest version
Directive 2011/62/EC	EU Directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products	2011

Index		
Standard	Title	Version
RTCA-DO 160	Environmental Conditions and Test Procedures for Airborne Equipment	Latest version
StrlSchG	German national Act on the Protection against the Harmful Effect of Ionising Radiation (Radiation Protection Act – *Strahlenschutzgesetz* – StrlSchG)	Latest version
StrlSchV	German national Ordinance on the Protection against the Harmful Effect of Ionising Radiation (Radiation Protection Ordinance – *Strahlenschutzverordnung* – StrlSchV)	Latest version
TAMG	Act on Marketing Veterinary Medicinal Products and Implementing EU Regulations Concerning Veterinary Medicinal Products 1 (Veterinary Medicinal Products Act – *Tierarzneimittelgesetz* – TAMG)	Latest version
TAMKatV	Ordinance on criteria for the categorisation of veterinary medicinal products and veterinary technical products as prescription or over-the-counter medicines (Ordinance on the categorisation of veterinary medicinal products – *Tierarzneimittel-Kategorisierungsverordnung* – TAMKatV)	Latest version
Regulation (EU) 2016/425	EU Regulation on personal protective equipment and repealing Council Directive 89/686/EEC	2016
Regulation (EU) 2017/745	EU Regulation on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	Latest version
Regulation (EU) 2017/746	EU Regulation on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 210/227/EU	Latest version
Regulation (EU) 2019/4	EU Regulation on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC	Latest version

Index		
Standard	Title	Version
Regulation (EU) 2019/5	EU Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use	Latest version
Regulation (EU) 2019/6	EU Regulation on veterinary medicinal products and repealing Directive 2001/82/EU (28 January 2022)	Latest version
Regulation (EU) 2020/561	EU Regulation amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions	Latest version
Commission Implementing Regulation (EU) 2021/2226	Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	Latest version
Regulation (EU) 2022/112	EU Regulation amending Regulation (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices and the later date of application of the conditions for in-house products	Latest version
Regulation (EU) 2023/607	Regulation (EU) of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices	Latest version
Regulation (EU) 2024/1860	Regulation (EU) of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of EUDAMED, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (text of relevance to the EEA)	Latest version

Index		
Standard	Title	Version
Regulation (EU) No 528/2012	EU Regulation on the placing on the market and use of biocidal products	Latest version
MPAMIV	German national ordinance on the reporting of suspected serious incidents involving medical devices and on the exchange of information between competent authorities (*Medizinprodukte-Anwendermelde- und Informationsverordnung* – MPAMIV)	Latest version

Sources

Document	Online source(s) (internet links in document)
AQAP Standards	http://nso.nato.int/nso/nsdd/listpromulg.html
DIN EN ISO standards	https://www.beuth.de
EU Guide to Good Manufacturing Practice (GMP)	https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/bekanntmachungen.html https://ec.europa.eu/health/documents/eudralex/vol-4_en
EU Regulations	https://eur-lex.europa.eu/
EUDAMED database	https://ec.europa.eu/tools/eudamed/#/screen/home
Documents of the European Medicines Agency (EMA)	https://www.ema.europa.eu/en
Harmonised EU standards	http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/
Information on Regulations (EU) 2017/745 and 2017/746	https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
German national laws and regulations	https://www.gesetze-im-internet.de/

Change procedure

The “Technical Specification: Quality Assurance Requirements for the Delivery of Medical Devices and Medicinal Products to the Bundeswehr” is a new Bundeswehr guideline.

- If any Bundeswehr contractors have suggestions for improvement, they can contact BAAINBw ZtQ1.3 once a year in January via professional associations (military technology, medical technology or pharmaceutical industry) to arrange for an appointment.
- Bundeswehr personnel are asked to contact BAAINBw ZtQ1.3 with any improvements that need to be incorporated.

Email: BAAINBwZtQ1.3@Bundeswehr.org