I. Company Identification			
1. Name	BGS Beta-Gamma-Service GmbH & Co KG		
2. Address	Fritz-Kotz-Straße 12		
3. City	Wiehl		
4. State / Zip Code	51674		
5. Telephone	+49 2261 7899-0		
6. FAX	+49 2261 7899-45		
7. E-mail Address	info@bgs.eu		
8. Company Website	www.bgs.eu		
II. Personnel Identification			
9. CEO	Dr. Andreas Ostrowicki		
10. QMR	Sarah Hauptmeier-Weber		
III. General			
11. What services are provided?	Radiations crosslinking and radiation of medical devices		
12. Hours of operation	Business Hours: 8 a.m. to 5 p.m.		
13. Number of Employees	209		
14. List of the different company locations and the general operations performed at each location			
51674 Wiehl, Fritz-Kotz-Straße 12 Tel. +49 (0)2261 7899 0	1x Gamma plant;	4x E-Beam plant 1x 0,5 MeV 1x 1,5 MeV 2x 3,0 MeV	
76646 Bruchsal, John-Deere-Straße 1+3 Tel. +49 (0) 7251 786 0	1x Gamma plant;	2x E-Beam plant 1x 4,5 MeV 1x 10,0 MeV	
93342 Saal a.d. Donau, Industriestraße 9 Tel. +47 (0)9441 1777 0		2x E-Beam plant 1x 5 MeV 1x 10 MeV	
15. Is the access to the facility controlled?		Yes	
16. Contact information for on-site audit	a) Name: b) Phone: c) Mail:	Marc Feldhaus +49 2261 7899-43 qm@bgs.eu	Burak Askeroglu +49 2261 7899 733
17. Is there business continuity or a disaster recovery plan?		Yes	
IV. Regulatory			
18. Has the facility been inspected by a government agency? a) Result:		Yes No warning letter or consent decree	
19. Last inspections			

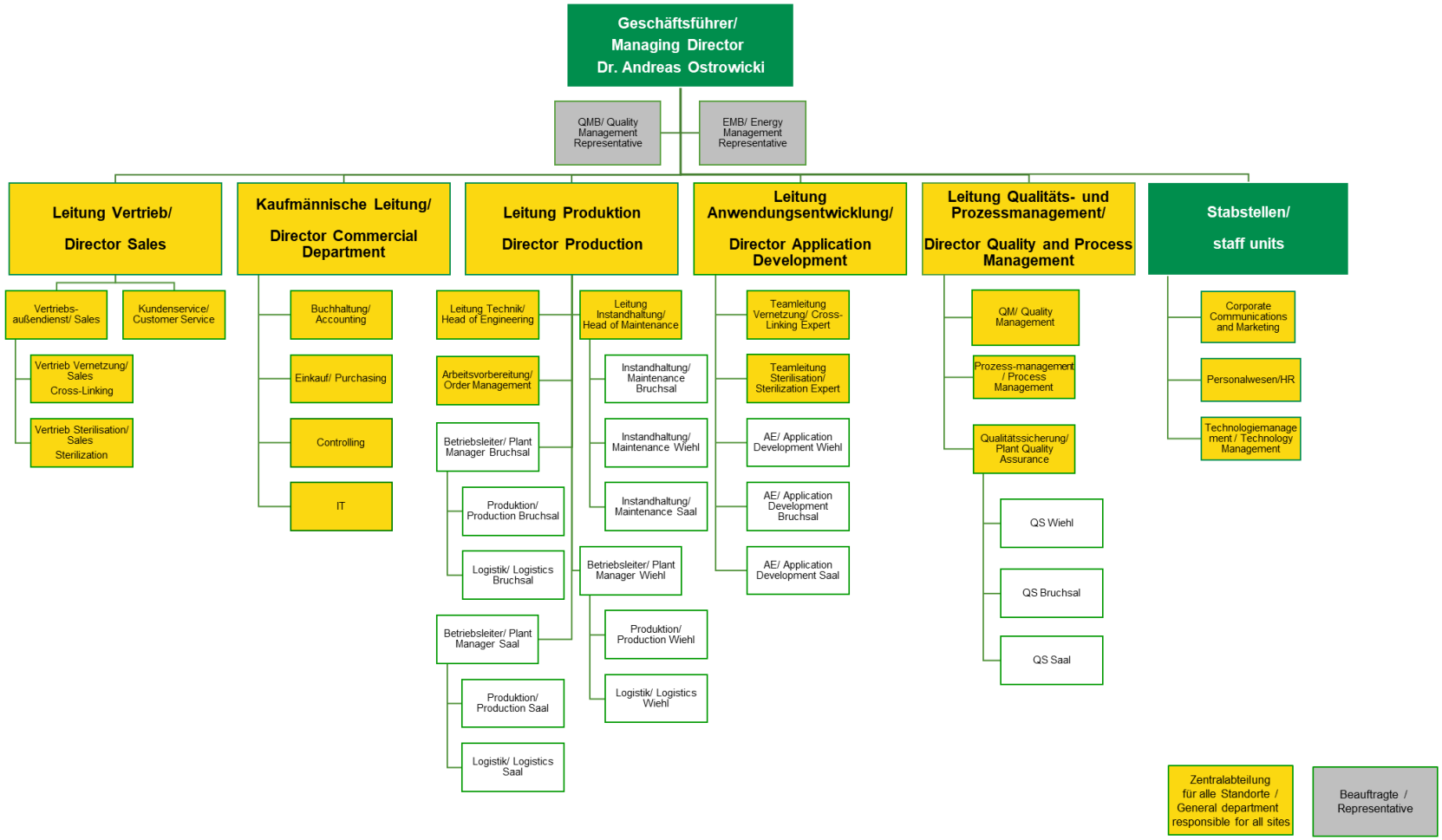
Agency	Reference	Date (year)	Result
DQS Med.	ISO 13485: 2016 ISO 9001: 2015 ISO 11137 1-3	2024	Passed

FDA (USA)	21 CFR 820 (QSR), USA 21 CFR 803 21 CFR 806	2015	Passed
FDA-Registration Numbers	Site-Wiehl: Site-Bruchsal: Site-Saal	3009732568 3005562917 3010288357	
Cosmos Corporation (RCB: Registered Certification Body, for the PMDA, Pharmaceuticals and Medical Devices Agency, Japan)	PAL / Ordinance No. 169, Japan	2012	passed
You can download our Certificates	https://de.bgs.eu/services/qualitaet-zertifizierung/		

V. Quality System	
20. Are there any externally granted certifications or licenses that the company maintains?	Yes ISO 9001: 2015 Yes ISO 13485: 2016 Yes ISO 11137: 2015 Yes ISO 50001:2018 Yes Japan Pal
21. Is the company part of a larger organization?	No
22. Is there a Quality Manual with a policy statement?	Yes
23. Are there procedures in place to perform internal quality system audits? a) Frequency	Yes Once a year
24. Are there suppliers / subcontractors? 25. Are there supplier assessments like audits or quality questionnaires?	Yes Yes
26. Is there an independent QA function?	Yes
VI. Standard Operating Procedures (SOP´s) and/or Policies	
27. Are there documented procedures for SOP´s and/or Policies?	Yes
28. The SOP´s are existing for the topics:	
• Organization and Personnel • Training • Responsibilities of QA • Internal audits • Batch release • Internal quality system audits • Corrective and Prevention Action • Good documentation practices • Order Processing • Production • Document Archiving • Equipment • Charge Control • Logistic Processes	
29. Are SOP´s and/or policies a) Documented approval by management? b) Periodically reviewed and updated? c) Maintained in a historic file? d) Marked with an effective date?	 Yes Yes Yes Yes
VII. Personnel Training Records	
30. Is there a formal documented employee training program?	Yes
31. Are there job descriptions detailing tasks and responsibilities?	Yes
32. Are training programs in place to ensure employees have the proper education/experience for their responsibilities?	Yes
33. Are training records maintained and available? 34. Are training records of past employees maintained and available?	Yes Yes

VIII. Equipment	
35. Is an inventory of equipment maintained?	Yes
36. Is there a documented certification/calibration system for all equipment used for measuring / testing? 37. Is it according to written procedures? 38. Are measuring/testing equipment re-certified and/or re-calibrated at documented intervals?	Yes Yes Yes
39. Is equipment subject to routine and non-routine maintenance? 40. Is it according to written procedures?	Yes Yes
41. Are training records maintained and available? 42. Are training records of past employees maintained and available?	Yes Yes
43. Is equipment traceable to national standards?	Yes
IX. Handling of customer product	
44. Is the Quality Assurance / Quality Control responsible for final approval of a product?	Yes
45. Are non-conforming or rejected products identified and segregated?	Yes
46. Is there a system in place to notify customers of a product specification change, product failure, recall, etc.?	Yes
X. Corrective/Preventive Actions	
47. Are there documented corrective/preventive action procedures?	Yes
48. Do corrective actions focus on preventing as well as repair/re-work?	Yes
49. Is there a system in place for documenting and assessing customer complaints?	Yes
XI. Computer Systems	
50. Are validated computer systems used to collect data?	Yes
51. Are electronic data considered raw data?	Yes
52. Are there policies/procedures on 21CRF Part 11/Annex 11 compliance? a) Are audit trails a part of the product/system? b) Are electronic signatures used? c) Are there security features incorporated in the system that would satisfy Part 11/Annex 11 requirements (i.e. password aging, inactivity timeouts, disabling user accounts, and detection of unauthorized access)?	Yes Yes Yes Yes
53. Are there logical security measures in place such as a) Unique ID and confidential passwords? b) Firewalls? c) Virus prevention, detection, and removal measures?	Yes Yes Yes
54. Do system or network administrators have access to these passwords?	Yes
55. Is there an inventory of computer systems?	Yes
56. Are data (electronic and/or paper) archiving performed and documented?	Yes
57. Are there back-up and restoration procedures for electronic data? 58. Are copies of software backups securely stored at an off-site location and protected from fire and other hazards?	Yes Yes

Annex 1: Organizational Chart



Annex 2: Audit Results of Audits of since 2013

DATE OF INSPECTION	AUTHORITY/ NATION	BGS SITE	REFERENCE	RESULT
March 18-22, 2013	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485	passed
March 25 – April 4, 2014	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485	passed
April 13-16, 2015	FDA (USA)	Saal a.d.D.	21 CFR 820 (QSR), USA 21 CFR 803, 21 CFR 806	passed
March 16-24, 2015	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485,	passed
March 15-22, 2016	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485,	passed
March 13.-22,2017	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485,	passed
March/August 2018	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed
March/August 2019	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed
March/August 2020	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed
February 2021	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed
February 2022	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed
February/March 2023	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed
February/April 2024	DQS Medizinprodukte GmbH	Wiehl, Saal a.d.D., Bruchsal	ISO 13485:2016 ISO 9001:2015 ISO 11137 1-3	passed

Date / Signature

20.03.2025

i.A.

X

Burak Askeroglu
Quality Management