QUALITY ASSURANCE AGREEMENT (QAA)

between

Ottobock SE & Co. KGaA
Max-Näder-Strasse 15
37115 Duderstadt

Otto Bock Healthcare Products GmbH
Brehmstraße 16
1110 Wien
Dokument: FO261 V11

Otto Bock Austria Gesellschaft m.b.H.
Brehmstraße 16
1110 Wien

Otto Bock HealthCare Deutschland GmbH
Max-Näder-Strasse 15
37115 Duderstadt

Otto Bock Mobility Solutions GmbH
Lindenstraße 13
07426 Königsee-Rottenbach
Dokument: 0253-SP01-F02c

Otto Bock Manufacturing Königsee GmbH
Lindenstraße 13
07426 Königsee-Rottenbach

-hereinafter OTTOBOCK-

and

Name and address of Supplier

-hereinafter Supplier-

Version ( )

ottobock.

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Quality for life

Preamble

In view of fierce national and international competition, quality and reliability are two decisive factors to ensure shared business success and good, fair and lasting cooperation between the Supplier and OTTOBOCK.

The high quality of the products is a basis of successful business activity and is greatly influenced by the quality of the supplier products. Assurance and continuous improvement of quality is the responsibility both of all employees and all suppliers of the company OTTOBOCK. To meet these requirements over the medium and long term, it is indispensable for partners of OTTOBOCK to be competent, reliable and quality-conscious.
This Quality Assurance Agreement (hereinafter QAA) defines such technical and organisational conditions and processes between the Supplier and OTTOBOCK as are necessary to achieve the intended target of zero defect quality. It regulates the rights and duties of the parties hereto in respect of the product quality of the parts supplied.
We consider our suppliers our partners. This QAA is to help to avoid quality problems and ensure smooth processes between the Supplier and OTTOBOCK and to minimise quality-related costs.

1 Scope

This QAA applies to all products delivered by the Supplier on the basis of the purchase order (deliveries, services) which he receives and accepts from OTTOBOCK for the duration of this Agreement.

2 Specification

The products and/or services ordered by OTTOBOCK must comply with the agreed specification (e.g., drawings, datasheets, etc.) and/or the agreed samples, which also applies to parts from subcontractors.
In each case, the Supplier will immediately check whether the documents made available are obviously flawed (obvious inaccuracies, ambiguous and/or contradictory information, feasibility and completeness), unclear, incomplete or obviously deviate from the sample. If the Supplier finds that this is the case, he will notify OTTOBOCK immediately in writing.
Any deficits identified shall be rectified immediately, and documented accordingly, in coordination between OTTOBOCK and the Supplier.

3 Production / service delivery

3.1 Production responsibility

The Supplier is responsible for the proper delivery of the products in accordance with the specifications and required quality as well as the handling of any means of production or products provided by OTTOBOCK and the control of the production process.
The Supplier shall be subject to the zero-defect target and shall continuously monitor and optimise his performance accordingly.

3.2 Long-term availability of starting materials / raw materials

The Supplier is responsible for ensuring the long-term availability of starting materials and/or raw materials. Any changes in this respect shall be notified in advance (at least 6 months).

3.3 Personnel

The Supplier shall ensure the proper training of all such employees as are charged with tasks affecting quality. Employees who carry out specially assigned tasks shall be qualified for such tasks on the basis of proper training, education and/or experience in accordance with the specific requirements. Proof shall be provided if so requested.

3.4 Identification and traceability

OTTOBOCK, as a manufacturer of medical devices, shall guarantee the appropriate traceability of its products so as to facilitate any corrective measures on the part of OTTOBOCK if necessary.
The Supplier shall prepare complete and unambiguous manufacturing documentation for every finished product batch. The manufacturer's documentation shall indicate or refer to: valid specifications for the finished product batch, materials used, production quantity and date of manufacture.
The supplier manufacturing documentation of the finished products shall be such that it allows for tracing the specifications according to which the product has been made. This supports traceability for OTTOBOCK if necessary.
Additional requirements for batch labelling and/or batch organisation are defined by OTTOBOCK in a product-specific manner if required and specified in the procurement documentation (purchase order).
In the inventory management of components (materials, individual components, assemblies or customer-provided components) for the manufacture of the contractual product, the Supplier shall ensure that the 'first-in/first-out' principle be complied with.
If the Supplier intends to irreversibly and directly affix batch numbers to components of the contractual product, customer-provided components and/or the contractual product itself, this shall be coordinated beforehand with OTTOBOCK with respect to possible adverse effects on the contractual product and shall be approved by OTTOBOCK in writing.
Where the manufacture of the contractual product involves the use of OTTOBOCK-provided components, the delivery documentation shall also reflect the batch numbers of such provided parts, specified by OTTOBOCK at the time of the provision, as well as the quantity of the provided parts used.
The labelling of the products and, if applicable, the packaging shall be adhered to by the Supplier in accordance with the agreed specification.
It shall be ensured that the labelling of the packaged products is legible at all times, also during transport and storage. Deviations from the labelling requirements shall be subject to a written agreement.

By labelling the products or the packaging, or by way of other suitable measures, the Supplier shall ensure that, in the event of a defect in the products, it is immediately possible to determine which other products or product batches may be affected.
In the case of a quality problem, batch and production data shall be accessible within one working day.

3.5 Production conditions

Products shall be manufactured and packaged under clean conditions. If necessary, the Supplier shall take appropriate measures to ensure that the product quality is not impaired by controlled environmental conditions (ESD protection or similar) at the place of manufacture. Special requirements (for example, particle contamination, defined room classes, product cleaning procedures, etc.) are agreed on a product-specific basis in writing as needed.

3.6 Facilities and equipment

The facilities and equipment used by the Supplier, including utility services, shall be adequate and suitable for the manufacture of the products. The Supplier undertakes to use only qualified equipment and to have in place an appropriate maintenance and calibration programme for the manufacture, including quality control, of the products. The Supplier further guarantees that no contamination of the products can occur following maintenance and repair work.

3.7 Sub-mixing / contamination

In order to avoid mixing of products of different geometry or identical geometry, but of other materials, appropriate technical, organisational and facilities-related measures shall be taken. In addition to the production of the products, this shall also apply to testing and the packaging process.
The corresponding production lines and workplaces shall be cleaned to remove the material from a previous production order before processing a new production order.

4 Quality assurance

4.1 Quality management system

The Supplier shall maintain a documented quality management system and shall develop, manufacture and test the products in accordance with the requirements of such quality management system.
Certification according to an international quality management standard such as ISO 9001 addresses the essential elements of this Agreement. It is recommended to aim for and maintain quality management system certification.
In addition, product-related, additional requirements, which are to be agreed in writing (e.g., by purchase order specification), may be necessary for the Supplier's quality management system (e.g., in accordance with ISO 13485, GMP).

If the Supplier has a certified quality management system, evidence of the establishment and maintenance of the quality management system introduced shall be provided by way of valid certificates issued by an accredited institution and any change in certification status reported in writing to OTTOBOCK.

The expiry of a certificate without planned re-certification, or a change in the scope of the quality management system that impacts OTTOBOCK products, shall be notified to OTTOBOCK at least 6 months before the expiry date. New certificates shall be sent unsolicited to OTTOBOCK. The revocation of a certificate shall be reported to OTTOBOCK immediately.

If no quality management system certification is available, the necessary measures for the qualification of the Supplier will be agreed between the contracting parties in writing, in accordance with the OTTOBOCK document "Supplier Self-Assessment".

4.2 Main contact for quality

The Supplier shall designate a quality assurance officer who can coordinate the execution of this Agreement and make or bring about related decisions.
In addition, further contact persons for quality assurance at the Supplier shall be named for the handling of critical quality processes and to ensure that the responsible individuals can be contacted for the prompt resolution of problems.

4.3 Subcontractors / subcontracting work to third parties

In the event that the Supplier receives production or testing equipment, software, services, materials or other subcontracting supplies for the manufacture or quality assurance of the products, he will contractually incorporate these into his quality management system, or even secure the quality of the supplies, taking into account the requirements of this Quality Assurance Agreement.
The Supplier's intention to have all or part of contractually agreed work carried out by third parties shall be subject to the prior written consent of OTTOBOCK.
The Supplier shall be solely responsible for the fulfilment of all contractual obligations to OTTOBOCK also in the event that he includes subcontractors. The Supplier shall be responsible for negligence of his subcontractors to the same extent as he is for his own negligence.

4.4 Changes / change management

The Supplier shall inform OTTOBOCK in writing about intended, quality-relevant changes to his quality management system as well as about changes to his relevant production factors and shall have OTTOBOCK approve them in writing before their implementation.
The changes requiring approval include in particular:

- Use of alternative materials or constructions
- Use of new or modified tools, or use of replacement tools
- Changes to manufacturing methods or production processes
- Relocation of production sites / production facilities
- Use of new production equipment (e.g., machines, tools)
- Commissioning or change of subcontractors
- Changes to procedures or facilities for testing products or other quality control measures.

4.5 Deviations identified by the Supplier

The Supplier maintains a system for managing deviations and for the effective introduction and monitoring of corrective and preventive measures. Such system shall ensure that internal and external quality information is collected and evaluated, that root causes are identified, and that sustainable remedial actions are taken to prevent the reoccurrence of problems.
If deviations from the agreed product or service specification (drawing, technical delivery conditions, specifications, material, material properties, etc.) or from approved processes occur during the manufacture of the products, the Supplier shall report them in writing to OTTOBOCK before delivery of the products.
In the interests of finding a prompt solution, the Supplier shall disclose the relevant data and facts.
The Supplier will continue the production and deliver the relevant products to OTTOBOCK only after OTTOBOCK has clarified the possibilities of reworking, or OTTOBOCK has granted special approval. Completed rework or special approvals shall be indicated in the supplier manufacturing documentation of the affected product batch.
The delivered goods shall be clearly identifiable as such in the delivery documentation in case of rework or special approval.
OTTOBOCK reserves the right to claim expenses from the Supplier for the technical clarification and verification of special approvals.
A special approval, however, does not release the Supplier from his fundamental responsibility for the zero defect quality of the products manufactured by him.

Where defective products have been delivered by the Supplier, OTTOBOCK shall be informed immediately in writing. OTTOBOCK will evaluate such deviation and inform the Supplier about the further procedure in writing.
If OTTOBOCK determines that an event or circumstance has occurred that necessitates a product recall in terms of the safety and/or quality of the products, the Supplier shall guarantee to OTTOBOCK that he will provide, within his means, the information necessary to carry out a targeted product recall promptly upon request.

In the event that OTTOBOCK has provided components and the Supplier determines that such components provided are faulty, OTTOBOCK shall be notified thereof immediately. Unless agreed otherwise, the Supplier and OTTOBOCK will contact each other immediately to determine the corrective action to be taken.
Following notice by OTTOBOCK, the Supplier shall carry out an inventory of the provided parts once a year and submit the result to OTTOBOCK in written form.
The following data shall be disclosed: number of units, batch number, effective date of the inventory and article number.

4.6 Documentation / information – reporting obligation

The Supplier maintains a system for the control of documents and data that renders the production processes and the specified properties of the products fully documented and traceable. The traceability of changes to the products and their manufacturing processes is of particular importance in this context.
The Supplier shall retain his own manufacturing documentation for at least 15 years following delivery of the finished products and shall share such documentation with OTTOBOCK if so requested.

4.7 Inspections / audits

OTTOBOCK reserves the right to determine whether the quality management system and the Supplier's production processes meet OTTOBOCK's quality and/or quality assurance requirements by means of an announced audit of the Supplier. The Supplier shall designate a qualified employee as a contact person during an audit.

The Supplier undertakes, if applicable and necessary, to take corrective action based on a mutually accepted audit report by OTTOBOCK. The Supplier shall grant OTTOBOCK the right to inspect subcontractors' audit reports for the contractual products in question.
The Supplier undertakes, if necessary, to have an audit conducted (at the production site of OTTOBOCK products) by the Notified Body / Certification Body of OTTOBOCK, or inspectors of monitoring authorities for medical devices (e.g., Food and Drug Administration / FDA). The Supplier shall ensure this equally for his subcontractors of OTTOBOCK products.

5 Quality audits at the Supplier

Through quality audits, the Supplier shall ensure that the zero defect quality of OTTOBOCK products is guaranteed. All quality audits carried out and their results are to be documented (CAQ system, process control chart, audit reports, etc.) and the records generated shall be submitted to OTTOBOCK upon request.

5.1 Testing means

The Supplier shall guarantee the availability at all times of all necessary testing equipment to examine the products to be manufactured for OTTOBOCK and shall ensure such equipment's continuous monitoring, calibration and maintenance.
If agreed in writing, the testing equipment and testing methods shall be coordinated between the Supplier and OTTOBOCK and, if necessary, a measurement calibration shall be carried out.
Unless agreed otherwise, process equipment (e.g., tools, devices) that OTTOBOCK has provided to the Supplier shall also be monitored and maintained by the Supplier.

5.2 Incoming goods inspection

The Supplier shall, at his sole discretion, ensure that materials and products procured by the Supplier comply with the agreed product specifications.

5.3 First-sample tests

As for the manufacture of initial and pilot series / test series to be monitored, the Supplier shall manufacture these products fully by means of serial resources and under serial conditions at the site of production.
For first-time pilot series, prior to the start of the first-time series delivery (initial series) or following modifications (pilot series/test series to be monitored), the Supplier shall send OTTOBOCK the affected products as pilot, initial or monitoring samples and submit a first-sample test report (FSTR), the content of which is coordinated in advance with OTTOBOCK.
The quantity of samples, the procedure / submission level (Annex 02) and the initial order (for pilot, initial and monitoring series) are agreed in writing between the Supplier and OTTOBOCK.

Upon OTTOBOCK's examination of the pilot, initial and monitoring samples and submission of a positive approval decision, commencement of series production shall be deemed approved by OTTOBOCK.
For the documentation of the pilot, initial and monitoring series sample inspection, either the OTTOBOCK form "First-sample test report" shall be used, or an equivalent document provided by the Supplier.
At the request of OB, a process capability study (PCS) shall be carried out. The process CP/CPK values targeted by OTTOBOCK are defined by OTTOBOCK and agreed with the Supplier.

5.4 In-process testing (IPT)

In order to ensure the qualitative uniformity of the production batches, the Supplier shall ensure appropriate monitoring of the production by means of controls of process parameters and essential quality characteristics.
A test plan shall be created for each product; it shall contain specifications on test criteria, tolerances, testing equipment, testing method, testing frequency and approval criteria. The Supplier shall grant OTTOBOCK access to these test plans upon request.
If the agreed quality is not achieved, the production process shall be optimised accordingly and quality shall be assured by way of suitable testing methods.

5.5 Final inspections / outgoing goods inspection at the Supplier

The Supplier ensures that the product fully complies with the agreed requirements and specifications (zero defect quality) before delivery of the products.
If 100% quality cannot be guaranteed by in-process quality measures, a final inspection shall be carried out.

Deliveries following a complaint by OTTOBOCK shall be subjected to a 100% final inspection for the next 3 follow-up deliveries.

5.6 Test certificate / acceptance test certificate

If agreed in writing, a test certificate according to EN 10204 /3.1 or /2.2 shall be submitted for each delivered product batch, which shows that the quality of the delivered products complies with the agreed specifications.

5.7 Archiving documentation pertaining to inspection and production data

Records generated for the manufacture and testing of OTTOBOCK products shall be retained for at least 15 years from the date of creation. Longer periods may be agreed in writing on a product-specific basis.

6 Packaging, transportation and scope of delivery

6.1 Packaging and transportation

The products shall be delivered in transportable and storable containers that ensure sufficient protection against quality reduction and contamination.
If agreed with OTTOBOCK in writing, specific packaging, labelling and transportation regulations shall be observed.

6.2 Delivery quantity

Delivery quantities can be ordered using quantity contracts with release orders or individual purchase orders. The delivery quantity agreed for a specific date shall be delivered as a connected delivery lot. Deviations require the prior written consent of OTTOBOCK.

6.3 Delivery documentation

Each delivery shall be accompanied by a delivery note and a Supplier Certificate of Conformance (CoC) with a clear reference to the purchase order and the delivered goods.
With the CoC, the Supplier shall certify in a documented form that the products named in the delivery note have been manufactured and packaged in full compliance with the OTTOBOCK specifications.
The delivery note and CoC can be attached to the delivery as separate documents or as a joint document.

7 Product complaints / complaints

7.1 Acceptance criteria

If OTTOBOCK discovers damage, defects or deviations from the agreed specifications, OTTOBOCK will immediately notify the Supplier in writing.

Should the defects or deviations cause damage to the products provided by OTTOBOCK or to other products in which the product is incorporated, the Supplier shall bear the resulting damage (such as material and labour).
OTTOBOCK reserves the right to reject entire deliveries or parts of deliveries and to demand immediate replacement deliveries without delay.

If OTTOBOCK identifies any defects during the inspection, OTTOBOCK shall be entitled to the statutory warranty rights without limitation.
Where OTTOBOCK insists on repairs or replacement, OTTOBOCK shall be entitled, until the full performance of the services/deliveries owed, to withhold the entire remuneration.
In the event of pending major economic damage or other damage, OTTOBOCK may rectify defects or have defects rectified, if – due to the particular urgency – it is no longer possible to inform the Supplier of the defect and the pending damage and/or to grant the Supplier a period of grace, albeit a short one, for rectification thereof in accordance with statutory provisions. Upon consultation, the costs of rectifying the defect may be passed on to the Supplier.
The further statutory rights of OTTOBOCK, for instance in the case of delays pertaining to rectification, up to and including claims of third parties, shall remain unaffected.
The Supplier shall maintain adequate insurance cover – usually EUR 5 million – and shall provide proof thereof if so requested.

7.2 Measures in connection with complaints

Complaints shall be processed by the Supplier in the form of an "8D report" and submitted to OTTOBOCK as a written statement within 30 working days (after receipt of the defective goods).
The immediate measures (8D report / sections D1 to D3) shall be communicated by e-mail within 3 to 5 working days and agreed with OTTOBOCK.
If the final statement cannot be prepared within 30 working days, immediate informal information on the status of the complaint processing shall be sent to OTTOBOCK.
The Supplier receives information from OTTOBOCK as to whether the defective goods can be processed, sorted out, reworked or scrapped subject to reservations.
If the Supplier causes work to be carried out by third parties (subcontractors), he will not be released from the responsibility of briefing, disposition and the necessary replacement delivery.

Subsequent deliveries from stock inventories and/or work-in-progress, which have been subjected to a 100% inspection due to a previous defect, shall be marked, unless otherwise agreed, with the form "Labelling tested goods after complaint" until proof the defect has been eliminated.
Initial deliveries after completing an 8D report based on a legitimate OTTOBOCK complaint shall be reported separately via the delivery documentation so that the effectiveness of corrective action taken by OTTOBOCK is plausible and verifiable.

In connection with legitimate complaints, OTTOBOCK is entitled to invoice the Supplier in respect of internal expenditure pertaining to documentation and creation in the amount of €150.00. The Supplier shall be free to prove that the damage suffered by OTTOBOCK was considerably lower. Further claims on the part of Ottobock, however, are not excluded.

8 Delivery agreement

All shipments and delivery notes shall be marked in such manner as to allow all products to be clearly identified at any time. The minimum information to be provided is the company name, article number, order number, quantity and batch number.
The date of delivery stated in the purchase order shall be the date on which the shipment shall be delivered to and received by OTTOBOCK. The purchase order and, in particular, the date of delivery stated therein shall be deemed accepted unless the Supplier objects thereto within 10 business days. Once the date of delivery has passed and no delivery has been made, the Supplier shall automatically be deemed in default. If there is prior knowledge of a delivery delay, the Supplier shall notify OTTOBOCK immediately. If such notice is not given, and this results in

production stoppage and/or delays in shipments, OTTOBOCK shall reserve the right to charge the Supplier for any resulting, additional costs. The right to withdraw from the Agreement with any grace period set by OTTOBOCK and to assert claims for further damages shall not be affected in the event of default.
The quality of the incoming shipments and products as well as adherence to schedule requirements will be assessed by OTTOBOCK. If there is a need for action following the supplier evaluation from OTTOBOCK's point of view, the Supplier will be informed immediately in writing.
In coordination with OTTOBOCK, the Supplier shall initiate appropriate corrective and preventive measures based on the reported results of the supplier evaluation, and inform OTTOBOCK in writing about the introduction and effectiveness of such measures.

9 Amendments and supplements to the Agreement

Amendments and supplements to this Agreement shall be made in writing and signed by both parties and will be incorporated into the Annex of this Agreement. This shall also apply to the requirement of written form.

Vienna, Austria,

Place,

OTTOBOCK

Head of Purchasing Department

Name Otto Bock:

Supplier

Commercial responsibility

Name:

Quality Management

Name Otto Bock:

Quality/Technical responsibility

Name:

Annex 1

Product guidelines and approval procedures

The following documents shall be submitted for sampling:
First-sample test report at least submission level 2, unless otherwise specified by OB.

		Submission level				
Item	**Scope where applicable to the product**	**0**	**1**	**2**	**3**	**Pilot series**
0	**Cover sheet of product and process approval report**	V	V	V	V	V
1	**Test results for product approval:** e.g., geometry, dimensions, function, material (strength, physical properties, etc.), weight, surface, ESD testing, electrical safety, etc.	D	V	V	V	V
2	**Sample** (Quantity and/or delivery quantity as per agreement)	D	V	V	V	V
3	**Technical specifications** (e.g., drawings, CAD files, specifications, approved design changes, short-circuit resistance, voltage protection, functional safety)	D	V	V	--	V
4	**Product FMEA**	na	na	*	*	na
5	**Design, development approval** Supplier's development responsibility accordingly at the Supplier	na	na	na	*	na
6	**Proof of compliance with OTTOBOCK specifications and/or statutory requirements** (e.g., environment, safety, recycling, country-specific certificates, ISO certificates, certificates from measurement and calibration institutes, etc.)	D	D	D	D	D
7	**Material master data sheet**	na	na	na	*	na
8	**Software test report**	na	na	na	*	*
9	**Process FMEA** (risk analysis)	D	D	D	*	*
10	**Process flow diagram** (manufacturing and test steps)	D	V	V	*	V
11	**Production control plan**	D	V	V	*	*
12	**Process capability studies**	*	*	*	*	*
13	**Evidence for securing special characteristics**	na	na	V	V	*
14	**List of testing equipment** (product-specific) Test/measurement certificates or acceptance certificates for gauges	D	D	V	V	V
15	**Testing equipment capability study**, where appropriate (results)	D	D	D	*	*
16	**Tool overview** (including number of pieces/number of cavities and information on tool concept)	D	D	V	*	V
17	**Proof of achievement of the agreed capacity**	*	*	*	*	*
18	**Parts history**	na	na	na	*	na
19	**Proof of suitability of the load carriers used** Including storage (packaging)	D	D	V	V	V
20	**Product and process approval status supply chain** (Supplier parts, set parts and in-house parts)	na	*	*	*	*
21	**Miscellaneous**	D	*	*	*	*

Legend:
V…Submission at OTTOBOCK
D… Execution, documentation and archiving at the Supplier (for inspection by OTTOBOCK if necessary)
na… not applicable
*… to be clarified with Supplier in advance

OTTOBOCK decides on the submission level (depending on the part(s)) according to the following selection criteria:

- Supplier QM System according to ISO 9001 and/or ISO 13485
- Classification of supplier status
- Part critical / non-critical (in terms of product safety)
- Experience with previous submissions
- Supplier know-how