Quality Assurance Agreement (QAA)

Company AG, [Address]

- **"[Supplier]"** -

and

Ypsomed AG, Brunnmattstrasse 6, CH-3401 Burgdorf

- **"Ypsomed"** -

The Parties are maintaining a business relationship regarding the supply of Products (as defined in Section 1). This QAA forms integral part of each order of Products from Ypsomed to [Supplier] and each delivery under such order.

Contents

1. Definitions and Abbreviations

Document/s	Electronical or paper document/s containing Information and data.
Non-Conforming Products	Products that do not fulfil the Specifications.
Line Clearance	Controls applied at the work place on a change of job in order to ensure a clean lot production.
Lot Documentation	Records that enable the individual steps to Product Provision to be traced. For details refer to Section 4.7.
Manufacturing Equipment	Manufacturing Equipment is used for Product Provision. The term includes machines, installations, systems, devices, production tools, etc. Manufacturing Equipment may consist of several devices in which particular technical processes take place.
Measurement and Test Equipment	Measuring devices or equipment used to take measurements, to make tests and to show Product conformity. This term includes rulers, callipers, timers, meters, electronic sensors, gauges etc.
Product Provision	All performance by [Supplier] and Sub-Suppliers for the acquisition, manufacture, testing, storage and delivery of Products.
Products	Goods ordered by Ypsomed and provided by [Supplier] for Ypsomed.
QAA	This Quality Assurance Agreement including Attachments. The term "QAA" also includes the documents referred to herein (such as e.g. Test Protocol).
Qualification	Written evidence showing that Manufacturing Equipment including subsidiary systems is suitable for fulfilment of the agreed requirements for Product Provision.
Quality Management System	A quality management system describes the requirements for the organisational structure, planning activities, responsibilities, methods, procedures, processes and resources for development, implementation, fulfilment, evaluation and maintenance of the quality of the Products.
Specifications	The current version of Ypsomed's written requirements for Product Provision, quality, materials, functionality, testing, lot size, packaging, labelling, storage, delivery, etc. that have to be met by each individual Product. The requirements are set out in this QAA and in further documents (such as for example purchasing specifications, technical specifications, drawings, production documents, Test Protocol and any test instructions).
Sub-Supplier	Third parties contracted by [Supplier] for the delivery of materials or components or for the performance of obligations in connection with Product Provision.
Validation Plan / Validation	Requirements and reporting document, which Ypsomed

Report	will provide to [Supplier] as required (e.g. for Test Run and Validation).
Test Run	In a Test Run a piece of equipment or a process is tested for its ability to achieve the agreed requirements for Product Provision.
Tools	Tools, models, forms, etc. that are specific to the Products.
Validation	Written evidence showing that all instructions, processes, equipment, materials and/or systems produce the expected results.

2. Scope of this Quality Assurance Agreement

This QAA forms integral part of each order of Products from Ypsomed to [Supplier] and each delivery under such order.

Ypsomed distributes medical products and accordingly is obliged to comply with relevant legal and regulatory requirements.

In the context of an up-to-date quality management, this QAA governs the legal and regulatory requirements that are to be observed during Product Provision. It sets out measures for ensuring the quality of Products. In addition, this QAA supports a high-quality commercial cooperation between the parties and governs responsibilities of the parties in connection with Product Provision.

The Parties undertake to cooperate in a continuous improvement process with the aim "zero defects in Product Provision".

3. Engagement of Sub-Suppliers Specifications

[Supplier] is entitled to engage Sub-Suppliers for the fulfillment of this QSV or each order respectively, provided however that Supplier approves such Sub-Suppliers according to a documented supplier evaluation system.

[Supplier] shall take all measures required to ensure the quality of the services of the Sub-Suppliers and in particular the quality of the materials and components that will be used for the manufacture of the Products. Such measures include but are not limited to incoming inspections, requirement of certificates of conformity. [Supplier] shall ensure that this QAA including its Attachment is observed and that its Sub-Suppliers are bound by the applicable provisions of this QAA accordingly. Upon request of Ypsomed [Supplier] shall provide written evidence regarding the observance of the requirements set out in this Section.

[Supplier] assumes full liability for the performance and all acts and/or omissions of its Sub-Suppliers, independently of whether Ypsomed has accepted the engagement of such Sub-Suppliers by written approval.

[Supplier] informs Ypsomed immediately in writing of any apparent contradictions in the requirements and unclear or incorrect information in the Specifications (if any).

4. Quality Assurance Measures

4.1 Quality Management System

Products may only be produced at production sites that have a certified Quality Management System pursuant to ISO 9001 / 13485 as updated from time to time. The additional requirements of ISO 13485 are to be fulfilled, as described in this QAA.

[Supplier] maintains the effectiveness of the Quality Management System for the entire duration of this QAA and ensures that it is applied without limitation to Product Provision for all Products.

The existence of the Quality Management System is to be evidenced by the relevant certificates pursuant to ISO 9001 / 13485. Copies thereof are attached to this QAA as **Attachment 1**. [Supplier] will provide copies of newly issued certificates (e.g. as a result of re-certification of [Supplier]) to Ypsomed automatically and without delay and will inform Ypsomed of all remarks of the certification body or other auditing bodies (such as authorities) concerning Product and validity of certificate automatically and without delay.

4.2 Risk Management

As a manufacturer of medical products, Ypsomed is obliged to operate a risk management system. This means that risk assessments are required.

[Supplier] will carry out risk assessments for the processes of Product Provision (e.g. FMEA) and keeps them up-to-date.

[Supplier] informs Ypsomed about possible risks of the Product and their elimination.

4.3 Documentation and Document Management

Product Provision must be planned and will be carried out under controlled conditions. Accordingly, [Supplier] is responsible for ensuring that all documents establishing and verifying the requirements for Product Provision are produced.

Such documents include, without limitation, Product specific documents relating to the processes:

- Development (sampling / verification, process validation)
- Production process from receipt of goods until delivery
- Change control
- Complaint handling / deviation management

[Supplier] is responsible for generating, documenting, controlling and updating all quality-related data (instructions, records and specifications).

The documentation is to be kept protected in such a way that it is available and readable for the entire preservation period and so that any alteration to it is evident.

[Supplier] will ensure that the Documents are preserved for at least fifteen (15) years after the last delivery of Product to Ypsomed, whereas the following rules shall apply:

a) Original Documents (in paper form) will be preserved for at least 7 years after the last delivery of Product to Ypsomed;
b) Prior to the expiry of the seven (7) year period set out in lit. a) above, [Supplier] will ensure that for at least another eight (8) years either (i) the Original Documents (in paper form) will be preserved under the same archival conditions or (ii) a verifiably identical electronical (e.g. pdf) copy of the original Documents will be preserved in a secure way.

If [Supplier] intends to destroy or delete the Documents on expiry of the overall fifteen (15) year period, it must first inform Ypsomed. Ypsomed may claim possession of the documents (in paper or electronical form respectively).

Upon termination of this QAA, [Supplier] provide the pre-mentioned Documents to Ypsomed. [Supplier] is allowed, but not obliged to keep one copy of such Documents.

4.4 Management of Resources

4.4.1 Personnel Resources

Personnel that carry out activities affecting Product quality must be qualified for performing those activities (e.g. on the basis of education, training, skills and experience).

4.4.2 Infrastructure and Work Place Requirements

Requirements for the health, cleanliness and work clothing of personnel are to be documented if contact between such personnel and the Product or the work place could affect Product quality.

In the event infrastructure or working environment have an influence on the quality of the Product, they have to be qualified and validated, respectively.

Maintenance activities, including frequency, are to be documented, where such activities or their absence could affect Product quality. Records are to be kept on these maintenance activities.

4.5 Change Control

All Product, production and process changes as well as changes to the infrastructure are to be documented.

All changes that have or could have an influence on Product quality are permitted only with the prior written approval of Ypsomed. These changes include, but are not limited to:

- Changes to the Product
- Changes to the Specifications
- Changes in production technology
- Moving production sites
- Changes to Manufacturing Equipment, Tools, test procedures
- Parameter changes outside the minimum and maximum values set during the most recent Validation
- Changes in and at Sub-Suppliers

4.6 Identification and Traceability

[Supplier] will ensure clean lot production. In order to prevent mix-up, a Line Clearance must be performed after each lot and documented in the Lot Documentation before a new lot can be started.

Materials, components, parts and Products are to be identified and marked by appropriate means according to Product status throughout the Product Provision (e.g. good, reject, rework, deviation, approved deviation, blocked). The scope of traceability and the required notation is to be set out in the procedures.

4.7 Lot Documentation

For each lot, records will be created and maintained. The records for a lot are to be verified and released.

The following is to be documented for each lot:

- Materials lots used
- Lot identification (lot number)
- Line Clearance (pursuant to Section 4.6)
- Accounting (quantities used, manufactured and released)
- Manufacturing Equipment, Tools, Measurement and Test Equipment used
- Test records (including test values and test results)
- Manufacturing parameters relevant for quality, including environmental conditions where relevant
- Personnel involved
- Removal of samples for retention

Ypsomed reserves the right to extent the nature and minimum contents of these records.

4.8 Marking of Packaged Units

A packaged unit may only contain Products from one and the same production lot. Unless otherwise provided in the purchasing specifications, each packaged unit is to be marked at least with the following:

- Ypsomed material description → for off the shelf product Supplier material description
- Ypsomed material number → for off the shelf product Supplier material number
- Number of units / use per packaged unit
- Date of manufacture
- Lot identification (lot number) [Supplier]/manufacturer

4.9 Accompanying Delivery Documents

4.9.1 Delivery Note

Deliveries must be accompanied by a delivery note, which, to the extent not otherwise provided in the purchasing specifications, must contain at least the following information:

- Delivery date
- Ypsomed order number
- Ypsomed material number
- Lot identification (lot number) [Supplier]/manufacturer
- Delivery quantity per lot
- Delivery note number(s)
- Manufacturing date
- Identity of manufacturer
- Drawing number with index [version]
- Material description

4.9.2 Certificate of Conformity / 3.1 EN 10204

A certificate of conformity is to be produced for each lot ("**Certificate of Analysis**" – "**COA**") ("**Certificate of Conformity**" – "**COC**") pursuant to the sample in **Attachment 2** to this QAA. A person independent of the production department ("**Independent Person**") must confirm that the Product was produced in accordance with the Specifications.

If required an inspection certificate in accordance with 3.1 EN 10204 may be requested upon mutual coordination.

4.10 Qualification, Test Run and Validation

In the event results of process outputs cannot be tested 100%, such processes must be validated. Validation shall be based on a well-established method (e.g. GHTF or FDA Guideline).

Repetitions of Qualification, Test Run, Validation, calibration and/or system analysis of the Measurement and Test Equipment are required on the following occurrences:

No.	Occurrence	Action
1	Changes to Products	Test Run, Validation
2	Changes in Sub-Suppliers	Test Run, Validation
3	Changes in production technology	Qualification, Test Run, Validation
4	Moving production sites	Qualification, Test Run, Validation
5	Introduction of new Manufacturing Equipment Changes to Manufacturing Equipment	Qualification, Test Run, Validation
6	Introduction of new Measurement and Test Equipment, changes to Measurement and Test Equipment	Calibration, system analysis
7	After a delivery freeze	Test Run, Validation
8	Process changes	Qualification, Test Run, Validation

4.11 Test instructions

Conformity of the Products with the Specifications is to be shown by way of testing.

[Supplier] will establish test instructions for all necessary tests, containing:

- Test methods

- Test indications and acceptance criteria
- Test strictness / intervals (taking of samples, conditioning of samples)
- Test steps
- Test procedure, Measurement and Test Equipment
- Nature of test record

Both parties undertake to co-ordinate the test instructions for the Products. Ypsomed reserves the right to prescribe Measurement and Test Equipment, test instructions and test methods.

The test instructions, as co-ordinated with Ypsomed, do not release [Supplier] from the obligation to establish further tests that may be necessary or desirable for specific processes. [Supplier] will ensure that the tests and test frequency are established and continuously amended in line with the quality of the process.

4.12 Tests

[Supplier] will ensure that all Products are subjected to the interim and final tests set out in the test instructions and to further tests established by [Supplier] for the specific process.

Records will be kept of the quality assurance measures, in particular regarding measurement values and test results. These shall identify the Measurement and Test Equipment used. The test records are part of the Lot Documentation.

The Measurement and Test Equipment used must be clearly identifiable and regularly checked and calibrated. Records are to be kept in this regard, enabling the results of checks and the test cycle of the Measurement and Test Equipment to be clearly attributed. [Supplier] will ensure that only Measurement and Test Equipment that meet the precision requirements are used.

5. Inspection by Ypsomed; Non-Conforming Products and Incidents

5.1 Inspection on Receipt by Ypsomed

Responsibility for carrying out the necessary inspections according to the provisions of this QAA lies with [Supplier]. Accordingly, Ypsomed will only inspect delivered Products in respect of:

- Identity
- Quantity
- Delivered documents (accompanying delivery documents pursuant to this QAA and the Specifications)
- Damage during transport that is apparent on the outside of the packaging.

Ypsomed expressly reserves the right to conduct additional inspections on receipt, but is not obliged to do so. In connection with the inspection on receipt, [Supplier] expressly releases Ypsomed from the duty to inspect and object pursuant to Article 201 and Article 367 of the Swiss Code of Obligations.

5.2 Product Defects

If during an inspection on receipt of Product or thereafter in the course of processing, a non-conformance to this QAA or the Specifications have been detected, Ypsomed is entitled to object to the defect and to return the entire lot.

Ypsomed will notify defects to [Supplier] normally within thirty (30) days of Ypsomed discovering or becoming aware of the main elements of the defect. Defects are generally deemed to be notified in due time if the respective notification to [Supplier] is provided during the warranty period as set out in the Specifications. In case no warranty period is set out in the Specifications, a warranty period of five (5) years from receipt of Product by Ypsomed shall be applicable.

[Supplier] is responsible for defective Products. Moreover, [Supplier] is obliged to deliver replacement Products free of defects, at its own cost and as soon as possible, however at the latest within three (3) weeks of receipt of the notice of defect. Ypsomed may also revoke the contract. Any other claims or remedies available to Ypsomed as a matter of law shall remain unaffected by this provision.

Ypsomed reserves the right in urgent cases to carry out the necessary sorting work of non-conforming Products itself or to have this done by a third party and to inform [Supplier] accordingly.

5.3 Measures

5.3.1 In the event of Non-Conforming Products

In the case of Non-Conforming Products or if incidents occur that could lead to Non-Conforming Products, [Supplier] will ensure that the cause of the error is found straight away. Appropriate measures for correction are to be taken (if applicable with Ypsomed's prior written approval, see Section 4.5) and their effectiveness is to be assessed. [Supplier] will inform Ypsomed in writing immediately.

5.3.2 In the event of Ypsomed's notices of defects

At the latest on the third (3) working day after receipt of the notice of defects from Ypsomed, [Supplier] will inform Ypsomed in writing about the details of the immediate steps taken and planned. [Supplier]'s written analysis of the cause and determination of further measures is to be received by Ypsomed within ten (10) working days after receipt of the notice of defects.

The notice of defects is to be worked into the form of a written complaint report (e.g. 8D-Report). The minimum contents of the complaint report are:

- Description of problem
- Immediate measures (including check of stock and work in progress, so that only Products free of defects will be delivered)
- Detailed root cause analysis
- Mid/long term measures for removing and avoiding problems
- Evidence of effectiveness / verification of corrective measures

The parties will agree in each case on the deadline for delivery of the complaint report to Ypsomed.

5.3.3 In the event of incidents

The parties are obliged to inform each other immediately about risks and functional breakdowns of the Product or similar products in the market that come to their attention. The duty to notify the European Vigilance System according to the European Guidelines 93/42/EWG pursuant to MEDDEV 2.12-1 or the national requirements (e.g. Art. 59 HMG Schweiz; Art. 14 and 15 MepV Schweiz) will be fulfilled by Ypsomed only. In the context of the required risk analysis of the incident, [Supplier] will immediately support Ypsomed with personnel with relevant expertise and make the requested documentation available.

5.4 Non-Conforming Product Costs

[Supplier] is liable for all costs in respect to to Non-Conforming Products. The rules on liability for costs also apply to risk analyses, root cause analyses and shipping costs. If Non-Conforming Products result in additional costs for Ypsomed, for example for sorting or reworking by Ypsomed or a third party, these additional costs will be borne by [Supplier].

6. Audit Right and Right of Access

Upon reasonable advance notice or in case of good cause on short notice [Supplier] shall grant Ypsomed, its notified body and the authorities responsible for Ypsomed's end product the right of inspection of all documentation mentioned in this QAA and shall make available all such documentation. If there are confidential documents or procedures that should not be reviewed by Ypsomed, these are expressly listed in **Attachment 3** to this QAA. These documents and procedures that are excluded from the right of inspection are however to be provided directly and without delay to notified bodies and authorities.

[Supplier] warrants that Ypsomed, its notified body and the authorities responsible for Ypsomed's end product are granted the right of access to the facilities relating to the Products. Ypsomed assures [Supplier] to keep confidential all findings resulting from such audits or inspections.

[Supplier] acknowledges that unannounced audits by notified bodies may be conducted without preliminary notice to [Supplier]. [Supplier] has knowledge of EU Commission Recommendation 2013/473/EU and accordingly [Supplier] is prepared to receive unannounced audits of notified bodies and to grant access to its facilities and to all documentation related to the Product Provision at any time].

In the event that the Products are placed on the market by and under the responsibility of a third party (other than Ypsomed) in its own name, such third party, its notified body and the authorities responsible for such third party's end product shall have the right of inspection and access set out herein.

In the event [Supplier] does not perform all or part of the obligations and duties under this QAA but has them performed by a third party, [Supplier] shall contractually oblige such third parties to grant the right of inspection and access as set out in this Section 6 to Ypsomed or the third party responsible for the end product.

7. Various

7.1 Term and Termination

This QAA enters into effect on the date or dates of signature by the Parties and shall continue in force for a period of [Period] years. If this Supply Agreement is not terminated by

either party by giving written notice to the other party at least XY months prior to the end of the minimum term, this QAA shall automatically continue unless terminated at any time by either party giving prior written notice to the other party at least XY months in advance. Unless otherwise agreed by the Parties, termination of this QAA automatically entails a termination of all orders of Product not receipt by Ypsomed at date of such termination

Either party may terminate this QAA at any time immediately without observing a notice period for an important reason; such as for example if:

a) an arrangement with creditors is made or an insolvency procedure is opened in respect of the assets of the other party or the other party is found unable to pay its debts, or

b) the other party breaches its obligations under this Supply Agreement and cannot remedy the breach within six (6) weeks of receiving written notice requiring it to do so, or

c) the manufacture and/or distribution and/or use of Products by Ypsomed and/or its customers is no longer possible in whole or in part as a result of an event of force majeure, a court decision, regulatory order or measures or for other important reasons.

7.2 Effects of Termination, Interpretation

Sections 4.3, 6 and 7 will remain in effect after the termination of this QAA.

If a provision of this QAA is or becomes invalid, the remaining provisions shall continue to be valid. Both parties are obliged to replace the invalid provision in a proper form with a valid provision that has a corresponding regulatory and/or quality assuring effect to that of the invalid provision. The same applies, if a provision proves to be unenforceable or in the event provisions required to be governed have been omitted.

7.3 Applicable Law, Jurisdiction

This QAA and each individual order of Products are governed exclusively by Swiss law, excluding the provisions of international private law. Any general terms of [Supplier] and The United Nations Convention on the International Sale of Goods are not applicable to this QAA nor to individual orders of Products.

The exclusive place of venue for all disputes shall be Burgdorf / Switzerland. [Supplier] hereby agrees that Ypsomed can also judicially institute legal proceedings against [Supplier] at the [Supplier]'s domicile.

Place, Date: [Supplier]

_____ _____ _____

Burgdorf, _____ Ypsomed AG

_____ _____ _____

Attachments:

Attachment 1: Copies of Certificates for Quality Management System (Section 4.1)
Attachment 2: Template Certificate of Conformity (Section 4.9.2)
Attachment 3: Procedures and Documents excluded from Ypsomed's Right of Review (Section 6)

ATTACHMENT 1

Copies of Certificates for Quality Management System (Section 4.1)

ATTACHMENT 2

Template Certificate of Analysis (Section 4.9.2)

Lieferant
Firma Muster AG
Adresse

Analysenzertifikat Certificate of Analysis

Kunde	_____	**Customer**
	_____	
	_____	
Material-Nr. YPS	_____	**Part # YPS**
Materialbezeichnung YPS	_____	**Part Name YPS**
Zeichnung-Nr. mit Index / Layout-Nr. mit Version	_____	**Drawing # with Index / Layout # incl. Version**
Chargenidentifikation (Chargennummer) Lieferant/Hersteller	_____	**Lot # Supplier**
Menge	_____	**Delivery Quantity**
Herstelldatum	_____	**Date of Manufacture**

Test	**Spezifikation / Toleranz**	**Anzahl Prüfmuster**	**Ergebnis (Range)**	**Bewertung ok/nok**
Test	**Specification/ Tolerance**	**Amount Samples**	**Result (Range)**	**Judgement ok/nok**

Wir bestätigen hiermit, dass das Material gemäss den Spezifikationen überprüft und dokumentiert ist.

We confirm, that the material is tested and documented according to the Specifications.

Datum/Date

Unterschrift einer unabhängigen Person

Signature of an Independent Person

[Alternative: COC]

Lieferant
Firma Muster AG
Adresse

Konformitätszertifikat Certificate of Conformity

Kunde	_____	**Customer**
	_____	
	_____	
Material-Nr. YPS	_____	**Part # YPS**
Materialbezeichnung YPS	_____	**Part Name YPS**
Zeichnungs-Nr. mit Index	_____	**Drawing # with Index**
Chargenidentifikation (Chargennummer) Lieferant/Hersteller	_____	**Lot # Supplier**
Menge	_____	**Delivery Quantity**
Herstelldatum	_____	**Date of Manufacture**

Wir bestätigen hiermit, dass das Material gemäss den Spezifikationen überprüft und dokumentiert ist.

We confirm, that the material is tested and documented according to the Specifications.

Datum/Date

Unterschrift einer unabhängigen Person

Signature of an Independent Person

ATTACHMENT 3

Procedures and Documents excluded from Ypsomed's Right of Access (Section 6)

- none