QAA
Quality Assurance Agreement

1. Purpose & Objective
This Quality Assurance Agreement (QAA) regulates the regulatory obligations and responsibilities between the industry in its role as MANUFACTURER and the ophthalmic optics company in its role as DISTRIBUTOR related to medical device law - hereinafter referred to as MANUFACTURER and DISTRIBUTOR, each individually as PARTY or jointly as PARTIES.

This Quality Assurance Agreement creates an important prerequisite for a rule-compliant, economic and quality-assured cooperation between the PARTIES. The QAA is based on the relevant requirements of the relevant legal regulations and standards of medical devices. The requirements, responsibilities and obligations of the European Medical Device Regulation No. 2017/745 (hereinafter „EU MDR") shall be complied with by both PARTIES in their respective roles as MANUFACTURER and DISTRIBUTOR and shall be ensured by this mutually agreed QAA. In particular, conformity with the regulations and the quality of the ophthalmic optics products shall be ensured throughout the entire supply chain.

The ophthalmic optics products supplied by the MANUFACTURER serve to correct defective vision or to compensate for functional deficits of the eyes. With regard to these medical devices, the MANUFACTURER shall comply with the necessary regulatory requirements of Regulation (EU) 2017/745 MDR and applicable harmonised standards.

2. Scope of Application
The subject matter of this QAA comprises all medical devices listed in the price list valid at the time of purchase by the MANUFACTURER, which the DISTRIBUTOR purchases from the MANUFACTURER to make available on the market. This QAA also covers all services required by the DISTRIBUTOR in connection with the provision of the said medical devices on the market (e.g. fitting).

Both PARTIES regard „making available on the market" to mean any supply of a device for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge, excluding test devices for clinical tests (cf. Item 27 Article 2 of the EU MDR).

3. Effective Period of this Quality Assurance Agreement
This QAA is entered into by the PARTIES for the entire term of the business relationship between the MANUFACTURER and the CUSTOMER and thus applies to all orders and purchases of medical devices by the DISTRIBUTOR in accordance with the product price list provided by the MANUFACTURER. Both PARTIES thus declare this QAA to be binding for the term of their business relationship and, in addition, for the fulfilment of their regulatory obligations under medical device law.

4. Contract Duration
The QAA shall have the same term as the underlying agreements under commercial law or as long as the business relationship between the MANUFACTURER and the DISTRIBUTOR exists and orders or product purchases are made by the DISTRIBUTOR from the MANUFACTURER according to the product price list.

Even after termination of the business relationship under commercial law, the relevant provisions of this QAA (product complaints, reporting obligations, cooperation with the competent authorities) as well as the provisions of the EU MDR regarding retention periods, information and other relevant obligations for the PARTIES shall continue to apply.

5. Content of this QAA
5.1 Receiving inspection, rejections
The MANUFACTURER shall deliver the products in suitable packaging chosen by it - unless the packaging is defined otherwise in consultation with the DISTRIBUTOR - which is intended to prevent transport damage when properly transported by a professional transport service provider. The packaging must comply with the valid, statutory disposal regulations of the country of manufacture.

The MANUFACTURER shall enclose with each delivery the necessary information to enable the DISTRIBUTOR to identify it, allocate it to the order and check it for transport losses. This includes at least a delivery note with order number, article number (if available) and quantity details.

5.2 Declarations of conformity
Before the DISTRIBUTOR makes the medical devices obtained from the MANUFACTURER available on the market, the DISTRIBUTOR shall verify that all of the following requirements are met:

- The medical device or its packaging bears the CE marking.
- The MANUFACTURER has issued and keeps available for inspection an EU declaration of conformity for the medical device.
- The medical device is identifiable and the MANUFACTURER has issued a UDI-DI for the medical device, if applicable.

To verify these requirements, the DISTRIBUTOR may use a sampling procedure that is representative of the medical devices supplied to it by the MANUFACTURER.

5.3 Documentation, archiving
The MANUFACTURER shall prepare the technical documentation in accordance with the requirements of medical device law and all other documents required by the regulations. He shall keep all documentation available for inspection by authorities for at least ten years after the last product covered by the EU declaration of conformity has been placed on the market.
The MANUFACTURER shall make the following documents available to the Distributor:

- The EU declaration of conformity (on request)
- Information relevant for lenses / frames according to Annex I Section 23 of the EU MDR.

In product catalogues as well as - where legally required - on product information, on the website and on the packaging, the necessary information for the identification of the product and the MANUFACTURER is provided for each product, as well as any information relevant for the user or, where applicable, third parties on the safety and performance of the product, as well as restrictions of use, precautions or warnings.

The DISTRIBUTOR shall document

- The written prescription,
- Fitting data, if these are not part of the written prescription,
- Information necessary to identify the patient or user,
- Information necessary to identify the device being fitted, and
- A statement that the device has been adapted in accordance with the current state of the art.

The DISTRIBUTOR shall properly store said documentation for ten years and submit it to the competent authority upon request. In order to support the DISTRIBUTOR in its obligation to keep a register of complaints, of non-compliant products and of recalls and withdrawals (Article 14, paragraph 5 of the EU MDR), this register shall be kept by the MANUFACTURER. For this purpose, the DISTRIBUTOR shall forward complaints and reports of suspected incidents by patients or users in connection with a product purchased from the MANUFACTURER and then made available, to the MANUFACTURER without delay and shall provide all information to the MANUFACTURER upon request.

5.4 Marking and Traceability
The MANUFACTURER shall provide the following information as part of product labelling (in accordance with the items applicable to lenses and frames in EU MDR Annex I, Section 23.2):

- The name, type or trade name of the product.
- Any essential information enabling the user to identify the product.

In the case of spectacle lenses, all of this comprises information according to DIN EN ISO 14889 point 6, which must be indicated on the lens bag:

- o Indication whether the lens is a right or a left lens, if applicable.
- o Refractive power and near addition in dioptres (sph, cyl, axis, add, prism, base)
- o Prismatic effect of the prism addition for multifocal lenses, if applicable
- o Position of the distance reference point for aspherical multifocal lenses
- o Nominal size in millimetres
- o Dimensions of the additional part for multifocal lenses in millimetres
- o Colour, if applicable
- o Name of the coating
- o Trade name of the material or/and the refractive index
- o Target peak refractive index (=measured values) where applicable
- o Method of measuring the near addition, if not the method using the surface on which the near addition is located

For spectacle frames, all of this is information according to DIN EN ISO 12870 item 9, which must be indicated on the spectacle frame:

- o Model name
- o Colour
- o Lens length with box symbol
- o Distance between the lenses
- o Total temple length
- o The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business.
- o The batch number or serial number of the product
- o The date of manufacture
- o Information on the packaging marking the product as a medical device.
- o CE marking
- o The UDI-DI from 26.05.2025 at the latest.

For this purpose, the symbols according to DIN EN ISO 15223-1 (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied) can be used:

Manufacturer	
Authorised Representative in the EU	
Importer	
Distributor	
Date of manufacture	
Medical Device	
Lot number	
Catalogue number	
Serial number	
Unique Device Identifier	

The DISTRIBUTOR shall verify that the marking is complete. The MANUFACTURER shall ensure traceability via the lot number / serial number / order number and - as soon as available - via the UDI-DI.

5.5 Storage, packaging and further transport
There are no special storage and transport conditions for spectacle lenses and frames except for protection against mechanical damage. In this respect, these products should be stored in a closed, dry and, if necessary, temperature-controlled room and transported in suitable packaging designed to protect against mechanical damage.

5.6 Hand-over of the products to the Final User
The DISTRIBUTOR shall instruct the Final User (FU) in the proper use of the eyewear, including correct care and handling.
The DISTRIBUTOR shall inform the FU of any limitations of use and risks. In particular this includes:

- Restrictions on driving a motor vehicle;
- Advice that spectacle lenses are generally not unbreakable.

The MANUFACTURER shall provide the DISTRIBUTOR with all necessary and important information (fitting instructions, instructions for use, restrictions on use, warnings, etc.) as early as in its product catalogues (product price list, product information). This means that the DISTRIBUTOR is aware of the product features and can inform the FU of any limitations of use and risks before the glasses are ordered.
The DISTRIBUTOR shall provide the FU with a statement containing the following information when the adapted product is delivered:

- The written prescription,
- Fitting data, if these are not part of the written prescription,
- Information necessary to identify the device being fitted, and
- A statement that the product has been adapted according to the current state of the art (valid national or international standards generally reflect the state of the art).

Note 1:
Instructions for use are exceptionally dispensable for medical devices of classes I and IIa, if safe use of these devices without instructions for use is ensured. Since the glasses are delivered to the FU by professionals (opticians) and the FU is informed about the correct use, restrictions of use and risks, the safe use of the product is ensured even without instructions for use. Thus, lenses and frames are supplied by the Manufacturer without instructions for use.

Note 2:
Any subsequent processing of a lens by the optician (tinting, hard lacquer coating, anti-reflective coating, etc.) which goes beyond the rim of the lens as required by the frame shall be carried out under the optician‘s own responsibility and shall exclude any liability on the part of the manufacturer. The DISTRIBUTOR shall indemnify and hold the MANUFACTURER harmless in this respect.

5.7 Complaints (Incidents)
If the DISTRIBUTOR receives information from the market that a medical device placed by it on the market is the subject of a complaint, it shall immediately inform the MANUFACTURER so that the latter can initiate any necessary corrective measures. The DISTRIBUTOR shall provide the MANUFACTURER with all the necessary information about the product and the FU from its customer register in writing and in full.

5.8 Serious incidents and recalls
The DISTRIBUTOR shall immediately notify the MANUFACTURER if the DISTRIBUTOR considers or has reason to believe that a medical device produced by the MANUFACTURER which it has made available on the market is not in conformity with EU MDR 2017/745 and/or that the medical device presents a serious risk (It is expressly clarified, that the DISTRIBUTOR is obliged under EU MDR 2017/745 to immediately forward to the MANUFACTURER all complaints and reports from healthcare professionals, patients or users about serious incidents related to the medical device obtained from the MANUFACTURER).

The DISTRIBUTOR shall cooperate with the MANUFACTURER as well as with the competent authorities to ensure that, where necessary, the necessary corrective action is taken to restore the device‘s conformity, to withdraw it from the market or to recall it. The DISTRIBUTOR undertakes to provide the competent authority, upon request, with all information and documentation available to the DISTRIBUTOR and necessary to demonstrate the conformity of the medical device obtained from the MANUFACTURER. The DISTRIBUTOR shall immediately inform the MANUFACTURER of the competent authority‘s request. The MANUFACTURER shall work closely with the DISTRIBUTOR to process the competent authority‘s request as quickly as possible.

Appropriate or requested information can then be provided directly by the MANUFACTURER to the competent authority. The MANUFACTURER shall cooperate with the competent authorities, at their request, on any action taken to prevent hazards associated with products sourced from the MANUFACTURER and made available on the market. The DISTRIBUTOR shall, upon request, provide a competent authority with samples of the product free of charge or, where this is not practicable, provide access to the product. (The DISTRIBUTOR is obliged under the EU MDR to inform the respective competent authority in accordance with the EU MDR in the event of a serious risk. The MANUFACTURER undertakes to assist the DISTRIBUTOR in this case, in particular in communicating the exact details of the non-compliance and corrective actions already taken).

If the MANUFACTURER considers or has reason to believe that a medical device provided by it to the DISTRIBUTOR and thus placed on the market may not comply with the MDR 2017/745, it shall immediately take the necessary corrective measures to restore that device's conformity. The MANUFACTURER undertakes to inform the DISTRIBUTOR of the non-compliant device and, if necessary, to take the necessary corrective measures in cooperation with the DISTRIBUTOR. In the event of non-compliance with this QAA, the DISTRIBUTOR shall immediately inform the MANUFACTURER in writing of these facts and the resulting corrective measures.

6. Confidentiality / Secrecy and Data Protection

The PARTIES undertake to maintain secrecy with regard to confidential information concerning the other PARTY and to use such information only for the execution of this QAA and the purpose pursued thereby. „Confidential Information" comprises all information and documents of the respective other PARTY which are marked as confidential or are to be regarded as confidential due to the circumstances, in particular information on operational processes, business relations and know-how, as well as all work results. Both PARTIES undertake to impose the duty of confidentiality on all employees and/or third parties who have access to the confidential information. If confidential information is disclosed to the PARTIES by a third party, they must notify each other of this immediately, at least in text form. The PARTIES shall comply with the relevant data protection regulations. If possible, the PARTIES will not make personal data available to each other.

In the event that, contrary to expectations, personal data is nevertheless processed on behalf of the other PARTY (also referred to as the „Controller" in this data protection context), the contracted PARTY (also referred to as the „Processor" in this data protection context) shall conclude a Processor Agreement with the Controller within the meaning of Article 28 of the General Data Protection Regulation (EU GDPR). At the request of the competent authority, the DISTRIBUTOR may hand over all information and documents to the MANUFACTURER after consultation with the latter, provided that the information and documents available to the DISTRIBUTOR are necessary to prove the conformity of a medical device obtained from the MANUFACTURER. In this context, the MANUFACTURER and the DISTRIBUTOR shall cooperate closely with each other. Against this background, the MANUFACTURER shall provide the required information to the DISTRIBUTOR or the competent authority upon request. The DISTRIBUTOR undertakes to inform the MANUFACTURER without delay of the information and documents handed over to the competent authority.

7. Final Provisions

Individual provisions of this contract being or becoming invalid or void, shall not affect the validity of the remaining provisions of this QAA. The PARTIES undertake to replace invalid or void provisions with new provisions which do justice to the economic regulatory content contained in the invalid or void provisions in a legally permissible manner. The same shall apply if a loophole should become apparent in this QAA. In order to close said hole, the PARTIES undertake to work towards the establishment of appropriate provisions in this Agreement which come as close as possible to what the PARTIES would have determined in accordance with the meaning and purpose of this Agreement if the point had been considered by them.