Annex I
(OEM Devices)

to the

Quality Assurance Agreement
(QAA)

between

Carl Zeiss Meditec AG
<address of site>

and

Co. <NN>

Content

Preamble

The issues formulated in this annex to the Quality Assurance Agreement (hereafter referred to as QAA) are content of the already valid QAA. The regulations of the already existing QAA remain unaffected.

I.1 Documentation requirements

I.1.1. Regulations for the preparation, approval and maintenance as well as the location and availability of technical documents shall be agreed bilaterally and product specific between supplier and customer. Essential requirements according to Annex I of the Directive 93/42/EWG have to be documented. Furthermore the determination of responsibilities have to be defined.

I.1.2. The manufacturer of the OEM device shall have a certified quality assurance system according to Annex II, V of the Directive 93/42/EWG.

I.1.3. The supplier shall provide the certificate according to the MDD 93/42 EEC for the respective OEM device unrequested. In case of changes of the certificate regarding change of scope, influence on succeeding certificates and check of content of certificates, the customer has to be informed immediately. In case of updates of the certificate a unrequested forwarding is required.

I.1.4. The supplier shall document and provide an unequivocal proof of identity for the OEM device of the customer. Consequently the customer can create a direct link to the product which is placed on the market in its own name.
The supplier shall provide a written and authorized declaration of conformity which shows that OEM device and Private Label device are identic. Distinctions between those products have to be mentioned explicitly.

I.1.5. Supplier and customer shall arrange the respective interfaces and responsibilities for the respective product in written form.

I.2 Product realization

I.2.1. If the product realization of the OEM device is executed by the supplier in total, the supplier shall provide all the necessary information so the customer can conduct a planning of activities.

I.2.2. The supplier shall provide all the product specific information about instruction for use and labelling. This applies in particular if the supplier places an identical device on the market in his own name.

I.2.3. The supplier shall provide an unequivocal proof of identity for the OEM device of the customer to ensure traceability.

I.2.4. The supplier shall always be able to provide a proof of traceability of raw material and components for the OEM device.

I.3 Vigilance

I.3.1. The supplier shall provide the customer with market knowledge which affects his own device (device which is placed on the market in his own name) in addition to information about the OEM device.

I.3.2. The supplier shall provide timely information if findings or information is available that show that the product conformity of his own device or the OEM-device is or might be affected.

I.3.3. Changes that affect the Private Label device and/or the OEM device, especially corrective and preventive actions have to be submitted to the customer immediately. An implementation of the OEM device change without approval by the customer is prohibited.

I.4 Duration of agreement and termination

I.4.1. After the termination of the contract period between supplier and customer the supplier shall ensure collaboration at least in case of incidents, mandatory notification and recall.

I.5 Responsibility Matrix

Quality Management System	Requirement / document	Status	OEM	PLM	Remarks
General Requirements	*ISO 13485 certificate*	*mandatory*	*x*		
	Declaration of Conformity	*mandatory*	*x*		
	RoHS regulations,	*mandatory*	*x*		
	Confirmation of equivalency between original product and PLM product	*mandatory*	*x*		
	Contract PLM / OEM (QAA)	*mandatory*	*x*	*x*	
Document Control	*Provide certificates (ISO 13485, EC-Certificate etc.)*	*mandatory*	*x*		
	Check certificates (validity and content)	*mandatory*		*x*	
	Technical documentation (Preparation/Update/ Archive)	*mandatory*	*x*		
	Essential Requirements (Preparation/Update/ Archive)	*mandatory*	*x*		
	Definition of archive period at OEM site	*mandatory*		*x*	
Management Responsibility	*Verified with QM certificates*	*mandatory*		*x*	
Management Resources	*Contract with OEM*	*mandatory*	*x*		
	Definition of interface between OEM/ PLM	*mandatory*	*x*		
Product Realization - Planning	*Project Plan for OEM product*	*mandatory*	*x*		
	Risk Management Report	*mandatory*	*x*		
	Risk Management Plan	*mandatory*	*x*		
	Risk Analysis	*mandatory*	*x*		
	Risk Evaluation/ Approval of remaining risks	*mandatory*	*x*		
	Test reports - product verification	*mandatory*	*x*		

Product Realization – Customer orientated processes	*Release of OEM product according customer specifications (Design Validation)*	*mandatory*	*x*		
Product Realization - Design Control	*List of applicable standards and regulations*	*mandatory*	*x*		
	User information (User Manual)	*mandatory*		*x*	
	Intended use of Medical Device	*mandatory*	*x*		
	Labelling specifications	*mandatory*		*x*	
	Approval of Labelling	*mandatory*	*x*		
Product Realization - Purchasing	*Frame Purchase agreement*	*mandatory*	*x*		
Product Realization – Identification & Traceability	*Traceability of critical components*	*mandatory*	*x*		
	Product identification & Traceability	*mandatory*	*x*		
Product Realization – Measuring Devices	*Specification of the measuring system*	*mandatory*	*x*		
Measuring, Analysis and continuous improvement	*Contract PLM /OEM (QAA)*	*mandatory*	*x*		
Non-conforming products	*Contract PLM /OEM (QAA)*	*mandatory*	*x*		
Medical Device Vigilance	*Contract PLM /OEM (QAA)*	*mandatory*	*x*		
CAPA	*Contract PLM /OEM (QAA)*	*mandatory*	*x*		

Carl Zeiss Meditec AG
<Site>

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(……..) (……..)

Supplier: ……., (date)……..

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