ref:	Technical file:	Date:

1 Area of application

Evaluation of the product documentation in case of a Privat Label Manufacuter according to OEM procedure.
To apply with new certification applications and sample evaluations in the context of the regular surveillance. (for details, see document: **EK-MED 3.9 B 16)**

PLM: Privat Label Manufacturer (Customer of the OEM-PLM relation)
OEM: Original Equipment Manufacturer (Supplier of the OEM-PLM relation)

Note: Procedures in which the OEM procedure is not accepatable (manufacturer is not certified according to MDD for the device or supplier is only PLM itself) it has to be evaluated according to EK-MED 3.9.B17.

1.1 Company (PLM) / Device

Company:		
Assessor	Name	Signature
Device	Device name:	article number if applicable
Generic product group / subcategory		GMDN: UMDNS (alternative):
Classification 93/42/EWG, Annex IX	Class:	according to rule:
Description, intended use		

1.2 OEM / supplier

Company:		
Adress:	street, house number	ZIP code, city
Device:	device name:	article number if applicable

Case I a: OEM has an approved quality assurance system according to Annex II, V or VI; a product certification according to Annex II (4) or Annex III is not necessary	(x)
Case I b: OEM has an approved quality assurance system according to Annex II without (4) as well as EC Design Examination Certificate according to Annex II (4)	(x)
Case I c: OEM has an approved quality assurance system according to Annex V or VI as well as an EC Type Examination Certificate according to Annex III	(x)
Case I d: OEM has no certified quality assurance system, i.e. choosen conformity assessment procedure according to Annex III with IV or VII with IV.	
Case II OEM is not the manufacutrer by means of the Directive and does not have a certificate according to Directive 93/42/EEC for the device in question	

Case Id is not covered by the scope of DQS Medizinprodukte and therefore it cannot be offered.

In case II an audit at the production site has to be performed, see EK-MED resolution 3.9 B17 Edition April 2010.

A separate audit planning has to be made by DQS Medizinprodukte GmbH (remark: no OEM procedure).

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2 Roles and Responsibilities

2.1 Lead Auditor

The lead auditor is responsible for the evaluation of the QM system regarding the system documentation of the customer, the reference standards and regulations of the Directive 93/42/EEC.
He has responsibility for the working within the audit team and compliance with the DQS processes.
In case that the lead auditor is not the expert itself, he accepts the assessors' evaluation for the product documentation without reservation.

2.2 Assessor

He is responsible for the technical and in regards to the contents evaluation of product and process specific aspects of the QM system.

In case that the technical file evaluation in the context of the sample evaluation is being performed separately from the assessment of the management system on-site, the assessor informs the lead auditor about the result of the evaluation of the technical file.

3 Evaluation on fulfillment on the requirement of the minimum documentation

	Evidence	Revision / Date	Evaluation
3.1a in case: Ia Ib, Ic			
Application of the PLM for performance of conformity assessment procedure to the Notified Body			
Regulation of the responsibilities, i.e. in form of a „list of responsibilities“			
Documented QM system of PLM			
Declaration of conformity of PLM			
Valid certificate(s) according to 93/42/EEC of OEM for the device in question			
Issued by Notified Body:			
According to Directive 93/42/EEC Annex ?:			
Certificate No.			
Valid until:			
Scope of the EC Certificate covers the device in question?			
Declaration of conformity of the OEM device			

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	Evidence	Revision / Date	Evaluation
Declaration of compliance of the OEM, that the OEM device and Privat Label device are identical / identical apart from …			
Labelling and instructions for use of the Privat Label device (including intended use and application restriction) in comparison with the Directives' requirements			
Labelling and instructions for use of already approved OEM devices (including intended use and application restrictions) – for comparison with the OEMs' specifications			
Name and adress of OEM identical in certificate, declaration of conformity and OEM contract			
3.1b additional in case: Ib, Ic			
Report of the EC Design Examination of the OEM's Notified Body (in case Ic the report has to reflect the evaluation of the technical file)			
An extensive documentation out of which the Notified Body is able to retrieve the changes between the device compared with the OEM device			
On request the complete technical file of the OEM is available.			
3.2 OEM contract			
Contract dated:			
Scope of the agreement (devices / device groups in question)			
Period of validity of the agreement			
Detailled specification for each device			
Regulations who is responsible for which documentation (technical documentation, DHR (Device History Record), etc.) including storage times, even after end of the agreement			

ref: **Technical file:** **Date:**

	Evidence	Revision / Date	Eva lua-tion
Traceability of raw material and components			
Influence of the PLM on the product design			
Regulations on the procedure, on how changes to the device and in the manufacturing process can be initiated, approved, performed, documented and communicated			
Right for the Notified Body and Competent Authority of the PLM to access or for submission of the technical documentation			
Regulations regarding collaboration with incidents/ notification obligations/recalls, even after end of the agreement			
Right of access for the Notified Body and Authority to the manufacturing facilities of the OEM and his suppliers/subcontractors			
Information obligation with changes on the certificate status of the OEM and/or PLM			
Handling of customer complaints as well as corrective and preventive actions			
If need, matrix of responsibilities			
3.2 Technical documentation of the PLM			
Name and adress of „manufacturer“ by means of the Directive 93/42/EEC.	see 1.1		
Identification of the medical device, it applies for the documentation	see 1.1		
Name and adress of the sites in question (development, production)			
Name and adress of the Notified Bodies that are involved in any form	see 3.1a		
Description of the applied conformity assessment procedure	see 3.1a		

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	Evidence	Revision / Date	Evaluation
Declaration of conformity	see 3.1a		
Short description of medical devices			
Compliance of the essential requirements (annex I)			
Risk management documentation			
Product labelling	see 3.1a		
Instructions for use	see 3.1a		
Analysis of the relevant legal regulations, that are being applied			
Identification of the technical standards, that were applied to show conformity with the requirements			
Short description of the evaluations and tests that were performed prior to marketing			
Analysis of clinical data / clinical evaluation			

The results of the assessment regarding the documentation and the realization of the Directive requirements has to be documented as follows:

1 = fulfilled
2 = fulfilled, improvement potential detected – no effect on marketability
3 = partially fulfilled, not acceptable (see 370.1 Sec. 1.2.4)
4 = not fulfilled (see 370.1 Sec. 1.2.4)
n.a. = not applicable