DNV-GL

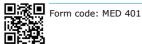
AUDIT REPORT MODULE D AND E

Directive 2014/90/EU (MED)

Parti	culars of a	audit					
Type o	f audit:			☐ Initial		Renewal	
Audit date:				2018-05-03			
DNV G	L auditor:			Andre Pfahl	ert		
DNV G	L station/sect	tion:		Essen			
Manufa	acturer:			ADOS GmbH Aachen			
Manufa	acturer's repr	esentative(s):		Michael Rütgers, Heinz Helmus, Andreas Winkens			
Parti	culars of c	certification	1				
Certifie	ed Quality Sys	y System: (e.g. ISO 9001) 🛛 Yes 🗌 No Certificate No: 01 100 71011		ate No: 01 100 71011			
Valid until:			29.05.2018				
Certified by:			TÜV Rheinla	and			
Standa	,		008				
Module	D/E Certifica	ate No. (if any):	:	MEDE00000	15 valid un	til 17.07.2022	
Modul Certifi	e B cate No(s).	MED Item No(s).	Product	(s)		Comments	
213.0		A.1/3.54	GTR 210	O XXXXXX ME	D	BG Verkehr (14.04.2020)	
Conc	lusion						
	The results of	of the audit are	satisfacto	ry for issuance	of module D	/E certificate.	
\boxtimes	The results of	of the audit are	satisfacto	ry for the mod	ule D/E certif	ficate to remain valid.	
\boxtimes	Nonconformities were not identified.						
	The following Nos. of findings (Nonconformities-NC and/or Observations-OBS) were identified: NC Category 1: NC Category 2: OBS: See overleaf Summary and the attached NC Notes.						
	The manufacturer will analyse the NCs, carry out corrective action and return the NC Notes within:						
	The auditor closed the NCs from last audit.						
	See commer	nts overleaf.					

The next audit is scheduled at: ADOS GmbH Aachen in 2019

Statement of confidentiality: This report, including any notes and checklists completed during the audit will be treated confidentially in accordance with the certification agreement.



Revision: 2016-12 www.dnvgl.com

Place: Essen Date: 2018-05-03



for **DNV GL**

Andre Pfahlert Auditor

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⊠Manufacturer	☑DNV GL section: Approval center (Incl.)
□Others:	checklist)
	NDNV GL local station: Essen

Comments:

Actually ADOS is changing the ISO 9001:2008 to the 2015 edition.

Findings

The nonconformities identified in this report do not necessarily represent the total number of nonconformities relevant for the quality system, the documentation or all departments.

Summary

	MED/ISO				Comments	Closed	
No.	9001 Ref.	1	2	Obs.	completion date		(date)

Classification

Nonconformity - Category 1 (Major)

- Significant doubts as to whether the product or service supplied will meet agreed requirements
- The total absence of the documentation and/or implementation of a required system element.
- A group of category 2 nonconformities within a single element of the audit standard.
- A category 2 nonconformity that is persistent shall be treated (up-graded) as a category 1 nonconformity.

Nonconformity - Category 2 (Minor)

 A lapse of either discipline or control during the implementation of the system/procedural requirements, which does not indicate a system breakdown or raise doubt that products or services will meet the directive and/or specified standards.

Observation

• A finding which may not significantly affect the quality system at that time, but which is judged by the auditor to be a potential concern. This includes comments on situations that are indicative of risk/hazard or notes for the attention of the manufacturer or the auditor for subsequent audits.

The manufacturer is not required to report handling of observations.

Form code: MED 401 Revision: 2016-12 www.dnvgl.com Page 2 of 2