AUDIT REPORT
MODULE D AND E

Directive 2014/90/EU (MED)

Particulars of audit

Type of audit:	☐ Initial ☒ Annual ☐ Renewal
Audit date:	**2018-05-03**
DNV GL auditor:	**Andre Pfahlert**
DNV GL station/section:	**Essen**
Manufacturer:	**ADOS GmbH Aachen**
Manufacturer's representative(s):	**Michael Rütgers, Heinz Helmus, Andreas Winkens**

Particulars of certification

Certified Quality System: (e.g. ISO 9001)	☒ Yes ☐ No Certificate No: **01 100 71011**
Valid until:	**29.05.2018**
Certified by:	**TÜV Rheinland**
Standard:	**ISO 9001:2008**
Module D/E Certificate No. (if any):	**MEDE0000015 valid until 17.07.2022**

Module B Certificate No(s).	MED Item No(s).	Product(s)	Comments
213.053	**A.1/3.54**	**GTR 210 XXXXXX MED**	**BG Verkehr (14.04.2020)**

Conclusion

☐ The results of the audit are satisfactory for issuance of module D/E certificate.

☒ The results of the audit are satisfactory for the module D/E certificate to remain valid.

☒ 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 comments overleaf.

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

Place: **Essen** Date: **2018-05-03**

for DNV GL
This document has been digitally signed and will therefore not have handwritten signatures.
Pfahlert, Andre
Surveyor

for **DNV GL**

Andre Pfahlert
Auditor

Enclosures:

Distribution

☒Manufacturer
☐Others:

☒DNV GL section: **Approval center** (Incl. checklist)
☒DNV 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

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

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.