AUDIT REPORT
MODULE D AND E

Directive 2014/90/EU (MED)

Particulars of audit

Type of audit:	☒ Initial ☐ Annual ☐ Renewal
Audit date:	**2019-09-04**
DNV GL auditor:	**Vagn Franzén-Andersen**
DNV GL station/section:	**M-ND-CMC**
Manufacturer:	**E-AT ApS**
Manufacturer's representative(s):	**Karen ,Jens, Kimmy,,Danny**

Particulars of certification

Certified Quality System: (e.g. ISO 9001)	☒ Yes ☐ No Certificate No: **0000545037-MSC-DANAK-DNK**
Valid until:	**2022-08-28**
Certified by:	**DNV GL BA**
Standard:	**ISO 9001:2015**
Module D/E Certificate No. (if any):	**MEDD00001WE (Draft)**

Module B Certificate No(s).	MED Item No(s).	Product(s)	Comments
as per MEDD			

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: **2**
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: **2020-09**

Place: **DK CPN** Date: **2019-09-04**

for **DNV GL**

Vagn Franzén-Andersen
Auditor

Enclosures:

Distribution

☒Manufacturer
☐Others:

☒DNV GL section: **A0702054** (Incl. checklist)
☐DNV GL local station: **A0702054**

Comments:

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.			
1						**Final DOC to be send to DNV GL**	
2						**Picture of Product marking to be send to DNV GL**	

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.