

Application AeMC Organisation Approval



Trafikstyrelsen
Danish Civil Aviation and Railway Authority

1 Applicant			
1.1 Applicant Data			
1.1.1 CVR Number			
1.1.2 Applicant Name (name of AeMC)			
1.1.3 Address (registered business address)	Street / Nr		
	Post Code		
	City		
	Country		
1.1.4 Contact Person (responsible for this application)	Title	<input type="checkbox"/> Mr.	<input type="checkbox"/> Ms.
	Name		
	First name		
	Job title		
	Phone/Fax		
	Email		
1.2 Aero-medical Centre (for which approval is requested)	<input type="checkbox"/> Same as Applicant Data in section 1.1 (→ continue with section 1.3)		
1.2.1 Aero-medical Centre Name	<input type="checkbox"/> Same as in section 1.1.2 Applicant Name		<input type="checkbox"/> Other (please specify below)
	Name		
1.2.2 Aero-medical Centre Address	<input type="checkbox"/> Same as in section 1.1.3 Address		<input type="checkbox"/> Other (please specify below)
	Street / Nr		
	Post Code		
	City		
	Country		
1.2.3 Use Annex I to list all medical and technical facilities related to the scope of approval including auxiliary clinical sites. (if different from 1.2)			
1.2.4 Use Annex II to list all medical and technical equipment related to the scope of approval, including at auxiliary clinical sites listed in 1.2.3			

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1.3 Billing Data		<input type="checkbox"/> Same as Applicant Data in section 1.1 (→ continue with section 1.4)	
1.3.1 Applicant Name	<input type="checkbox"/> Same as in section 1.1.2 Applicant Name		<input type="checkbox"/> Other (please specify below)
	Name		
1.3.2 Billing Address	<input type="checkbox"/> Same as in section 1.1.3 Address		<input type="checkbox"/> Other (please specify below)
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		
1.3.3 Contact Person (Financial)	<input type="checkbox"/> Same as in section 1.1.4 Contact Person		<input type="checkbox"/> Other (please specify below)
	Title	<input type="checkbox"/> Mr. <input type="checkbox"/> Ms.	
	Name		
	First name		
	Job title		
	Phone /Fax		
1.4 Certificate Delivery Data		<input type="checkbox"/> Same as Applicant Data in section 1.1	
1.4.1 Applicant Name	<input type="checkbox"/> Same as in section 1.1.2 Applicant Name		<input type="checkbox"/> Other (please specify below)
	Name		
1.4.2 Delivery Address	<input type="checkbox"/> Same as in section 1.1.3 Address		<input type="checkbox"/> Other (please specify below)
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		
1.4.3 Contact Person (Certificate Delivery)	<input type="checkbox"/> Same as in section 1.1.4 Contact Person		<input type="checkbox"/> Other (please specify below)
	Title	<input type="checkbox"/> Mr. <input type="checkbox"/> Ms.	
	Name		
	First name		
	Job title		
	Phone/Fax		
	Email		

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Applicant's Reference Please provide an individual reference to this application		
Identification of Activity		
<input type="checkbox"/> Initial Approval		
<input type="checkbox"/> Change Approval	NAA Approval N°:	
Intended commencement of activity on	(dd Month yyyy)	
2. Head of AeMC		
2.1 Name		
2.2 AME certificate reference		
2.3 Class 1 privilege since	(dd Month yyyy)	
3. Name of qualified AME(s) Use Annex III to list all qualified AMEs, other medical staff and supporting specialist consultants.		
4. Proposed administration documents and manuals submitted with application		
<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Management System documentation <input type="checkbox"/> Head of AeMC CV <input type="checkbox"/> Staff Training Records </div> <div> <input type="checkbox"/> Other Manual(s) <input type="checkbox"/> Documents of clinical attachment, or liaison with designated hospitals, or medical institutes Procedure describing how changes not requiring prior approval will be managed and notified to the competent authority (ORA.GEN.115, (b)) </div> </div>		
5. Details of proposed compliance monitoring system		
Item	Reference in the organisation's documentation	
5.1 Detailed description of the compliance monitoring function of the management system		
5.2 List, table or cross-reference indicating what means and methods are dedicated to achieve initial and continued compliance with each implemented requirement applicable to the organisation		
5.3 Means and methods establishing the internal audit process		
5.4 Means and methods establishing the feedback system of audit findings to the accountable manager		
5.5 Nominated person or group of persons, ultimately responsible to the accountable manager of ensuring that the organisation remains in compliance with the applicable requirements		
5.6 Means and methods making personnel aware of their responsibilities		

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5.7 Procedure for amending the documentation	
5.8 Means and methods to ensure initial and continued compliance of contracted activities	
5.9 Compliance with the requirement for the direct safety accountability of the accountable manager	
5.10 Compliance with the requirement for the organisation's safety policy	
5.11 Compliance with the requirement for the identification of aviation safety hazards entailed by the activities of the organisation (in terms of means and methods)	
5.12 Compliance with the requirement for the evaluation and the management of risks associated with the identified aviation safety hazards (in terms of means and methods)	
5.13 Compliance with the requirement for the actions to be taken to mitigate the risk and verify their effectiveness (in terms of means and methods)	
5.14 Compliance with the requirement for making personnel aware of their responsibilities as regards the safety functions (in terms of means and methods)	

<p>6. Notes</p> <p><u>If answers to any of the above questions are incomplete:</u> Please provide full details of alternative arrangements separately.</p> <p>Regulation (EC) No. 2018/1139 specifies that the Danish Civil Aviation and Railway Authority shall issue and renew the certificates of aero-medical centres located inside the territory of Denmark. Therefore please enclose with this application a copy of your Certificate of Incorporation (for profit organisations) or the equivalent official document (for non-profit organisations) confirming the legal status of your organisation.</p>
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7. Applicant's declaration and acceptance of the General Conditions and Terms of Payment		
<p>I declare that I have the legal capacity to submit this application to the Danish Civil Aviation and Railway Authority and that all information provided in this application form is correct and complete.</p> <p>I have understood that I am submitting an application for which fees or charges will be levied by the Danish Civil Aviation and Railway Authority</p> <p>I, the undersigned, on behalf of the applicant identified in 1.1.2 above certify that all the above named persons are in compliance with the applicable requirements and that all the above information given is complete and correct.</p>		
Date/Place	Name of Accountable Manager	Signature
<p>This Application with Annexes I-III and the additional document as outlined in Chapter 6 should be sent by e-mail or regular mail to:</p> <div><div>Trafikstyrelsen Carsten Niebuhrs Gade 43 1577 Copenhagen W Denmark</div><div>info@trafikstyrelsen.dk</div></div>		

PLEASE DO NOT FORGET TO SIGN THE APPLICATION FORM

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Annex I: List of medical and technical facilities including auxiliary clinical sites.			
Medical & technical facilities related to scope of approval & auxiliary clinical sites.			Type of Activity
1.	Name		<input type="checkbox"/> Clinical attachment <input type="checkbox"/> for initial class 1
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		
2.	Name		<input type="checkbox"/> Clinical attachment <input type="checkbox"/> for initial class 1
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		
3.	Name		<input type="checkbox"/> Clinical attachment <input type="checkbox"/> for initial class 1
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		
4.	Name		<input type="checkbox"/> Clinical attachment <input type="checkbox"/> for initial class 1
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		
5.	Name		<input type="checkbox"/> Clinical attachment <input type="checkbox"/> for initial class 1
	Street / Nr		
	PO Box		
	Post Code		
	City		
	Country		

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Annex II: List of medical and technical equipment, including at auxiliary clinical sites			
Medical & technical equipment related to scope of approval & auxiliary clinical sites.		AeMC	Contracted activity site
1. General medical practice			
2. Cardiology			
2.1. 12-lead resting ECG			
2.2. Stress ECG			
2.3. 24-hour blood pressure monitoring			
2.4. 24-hour heart rhythm monitoring			
3. Ophthalmology			
3.1. near, intermediate and distant vision			
3.2. external eye, anatomy, media and fundoscopy			
3.3. ocular motility			
3.4. binocular vision			
3.5. colour vision (anomaloscopy or equivalent)			
3.6. visual fields			
3.7. refraction			
3.8. heterophoria			
3.9. anomaloscope or equivalent (for Class 3 application)			
4. Hearing			
4.1. pure-tone audiometer			
5. Otorhinolaryngology			
5.1. otoscopy			
5.2. rhinoscopy			
5.3. tympanometry or equivalent			
5.4. clinical assessment of vestibular system			

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Annex II: List of medical and technical equipment, including at auxiliary clinical sites

[illegible]

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Annex III: List of qualified AMEs, other medical staff and supporting specialist consultants

	Identification and qualifications		Certificate & role	Type of Employment
1.	Name		Certificate Number:	<input type="checkbox"/> Full Time <input type="checkbox"/> Part Time
	Qualifications		<input type="checkbox"/> AME <input type="checkbox"/> Supporting specialist consultant	
2.	Name		Certificate Number:	<input type="checkbox"/> Full Time <input type="checkbox"/> Part Time
	Qualifications		<input type="checkbox"/> AME <input type="checkbox"/> Supporting specialist consultant	
3.	Name		Certificate Number:	<input type="checkbox"/> Full Time <input type="checkbox"/> Part Time
	Qualifications		<input type="checkbox"/> AME <input type="checkbox"/> Supporting specialist consultant	
4.	Name		Certificate Number:	<input type="checkbox"/> Full Time <input type="checkbox"/> Part Time
	Qualifications		<input type="checkbox"/> AME <input type="checkbox"/> Supporting specialist consultant	
5.	Name		Certificate Number:	<input type="checkbox"/> Full Time <input type="checkbox"/> Part Time
	Qualifications		<input type="checkbox"/> AME <input type="checkbox"/> Supporting specialist consultant	

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Completion Instructions for Application Form:

This Application Completion Instruction Sheet will provide you with any additional instructions and requirements necessary to complete the Application for an AeMC Organisation Approval. Please complete the form in a **clearly legible** way.

Chapter 1: Applicant

- 1.1.1 If known, please enter your danish customer number.
- 1.1.2 Please enter the full **name of the company** as it appears on the Article/Certificate of incorporation of the company. If applicable also enter the Trade Name, Doing-business-as and the Company registration number. In case the applicant is not a company but a **natural person**, please enter the full name as it appears in your ID Card/Passport.
- 1.1.3 Please enter the address of the registered office as it appears on the Article/Certificate of incorporation of the company. In case the applicant is not a company but a natural person, please enter the address at which you are registered.
- 1.1.4 The name and contact details specified in this section are those of the person responsible for the application.
- 1.2.1 The (company) name specified in this section will be printed on the certificate the Danish Civil Aviation and Railway Authority will issue.
- 1.2.2 The address specified in this section, the registered business address, will be printed on the certificate the Danish Civil Aviation and Railway Authority will issue.
- 1.3.1 The (company) name specified in this section will be printed on the invoice/s the Danish Civil Aviation and Railway Authority will issue.
- 1.3.2 The address specified in this section will be printed on the invoice/s the Danish Civil Aviation and Railway Authority will issue.
- 1.3.3 The name and contact details specified in this section are those of the person that will be contacted for all issue connected with the Danish Civil Aviation and Railway Authority invoices. (e.g. accounts payable clerk).
- 1.4.1 The (company) name specified in this section is where the Danish Civil Aviation and Railway Authority will send the original certificate/approval.
- 1.4.2 The address specified in this section is where the Danish Civil Aviation and Railway Authority will send the original certificate/approval.
- 1.4.3 The contact person of this section is the person the approval will be sent to.

Applicant's Reference: IMPORTANT: Please provide an individual internal reference to this application which you would like to see on all communication with the Danish Civil Aviation and Railway Authority.

Chapter 2. to 5.

- 2.1 Please provide the First Name and the surname of Head of AeMC
- 2.2 Reference of AME Certificate of the Head of AeMC
- 2.3 Date when AME Certificate of the Head of AeMC was extended to class 1 privileges
- 3. Please list in Annex III all qualified AMEs, other medical staff and supporting specialist consultants. This list shall match the lists in the manuals of the organisation.
- 4. Tick each relevant box to indicate if the document is joined to the application form.
- 5. For each item listed (**5.1 to 5.14**), provide the reference of the documented evidence available in the organisation's manuals or controlled documentation. AeMCs under Grandfathering shall enter the reference to their the relevant part of their implementing plan explaining how the organisation is going to adapt its management system, training programmes, procedures and manuals to be compliant with Part-ORA (Annex VII) by 8 April 2014 at the latest as required by Article 10c paragraph 2 of Aircrew Regulation (EU) 1178/2011 as amended by Regulation (EU) 290/2012
- 6. Do not forget to provide the copy of your Certificate of Incorporation or the equivalent official document confirming the legal status of your organisation.
- 7. Please make sure that the Accountable Manager signs the application form.

Carsten Niebuhrs Gade 43
1577 København V
Telefon 7221 8800
Fax 7262 6790
info@tbst.dk
www.tbst.dk

Personal Data Protection

According to the general data protection regulation (GDPR), we hereby inform you how we handle the personal data we receive and process about you.

We are the Data Controller - how to contact us

The Danish Civil Aviation and Railway Authority (hereafter the Authority) is the Data Controller for the personal data we receive on you. If you have any questions concerning our processing of your personal data by the Authority, you are welcome to contact us or our independent data protection adviser via the contact details below:

Contact details for the Danish Civil Aviation and Railway Authority:

Carsten Niebuhrs Gade 43
1577 København V
Tel.: +45 7221 8800
E-mail: info@tbst.dk
CVR no.: 27186386

Contact details for our data protection adviser:

E-mail: dpo@tbst.dk
Tel.: +45 41780531

Purpose of processing your personal data

The Authority processes personal data for the following purpose:
For the purpose of processing an application for a flight permit

Legal basis for processing your personal data

The legal basis for processing your personal data stems from:
The Cape Town Convention

Categories of personal data

The Authority processes the following categories of personal data on you:

Name, address, aircraft registration, documentation for authorization to sign for the company

Filing of your personal data

The data the Authority may keep on record are regularly forwarded to the Danish National Archives in accordance with the rules of the Danish Archives Act and the provisions laid down by the Danish National Archives. Data we receive that are not subject to the Authority's duty to keep records will be deleted when we no longer need them.

Your rights

According to the Data Protection Regulation, you have a number of rights regarding our processing of your personal data by us. If you want to exercise your rights, please contact us.

Right to see your data

You have the right to see the data we process on you (the right of access to documents), or to apply for access to documents.

Right of correction

You have the right to have incorrect data on you corrected.

Right of deletion

In special circumstances, you have the right to have data we have on you deleted before the date on which we generally delete data. This only applies to data which we are not obliged to record.

You can read more about your rights in the Danish Data Protection Agency's guide to data subject rights at www.datatilsynet.dk.

Complaints to the Danish Data Protection Agency

You have the right to complain to the Danish Data Protection Agency if you are dissatisfied with the manner in which we process your personal data. You can find the Agency's contact details at www.datatilsynet.dk.