



Certificate of compliance with Danish legislation on the Medicinal Cannabis Pilot Programme

On the basis of the inspection carried out by the Danish Medicines Agency the **22.08.2019**, in accordance with section 59 of the Act on a Medicinal Cannabis Pilot Programme (no. 1668 of 26/12/2017) the Danish Medicines Agency certifies that the site indicated on this certificate complies with:

Act on a Medicinal Cannabis Pilot Programme (no. 1668 of 26/12/2017) and Executive Order on Cultivation, Manufacture and Distribution of Cannabis Bulk and Manufacture of Cannabis Primary Products. (no. 695 of 03/07/2019).

Certificate no: **DK CMPF 00112025**

Manufacturer: **Schroll Medical ApS**

Site Address: **Kildegårdsvej 32
DK-5792 Årslev
Denmark**

The site is by national legislation mandated to comply with the following guidelines, and from the knowledge gained during inspection of this manufacturer The Danish Medicines Agency considers this site in compliance with:

- GACP – The Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin as adopted by The Committee on Herbal Medicinal Products (HMPC) under The European Medicines Agency
- EU GMP, vol. 4, Part I - The principles and guidelines on Good Manufacturing Practice laid down in Directive 2003/94/EC
- EU GMP, vol. 4, Part II - The principles of Good Manufacturing Practice referred to in article 47 of directive 2001/83/EC

This certificate reflects the status of the manufacturing site at the time of inspection noted above. This certificate is valid only when presented with all pages and until 31 December 2021 when the period for the pilot programme in Denmark ends. After this period new certificates may be issued. The authenticity of this certificate may be verified by the Danish Medicines Agency.

Type of products subject to inspection

Cannabis primary product

Restrictions or clarification

None



MANUFACTURING OF CANNABIS PRIMARY PRODUCTS	
2.1	Manufacture of cannabis primary products
2.1.6	Herbal tea
2.1.10	Preparations for inhalation
Packaging	
2.2	Primary packing of cannabis primary products
2.2.6	Herbal tea
2.2.10	Preparations for inhalation
2.3	Secondary packing of cannabis primary products
BATCH CERTIFICATION	
2.5	Batch certification of cannabis primary products
STORAGE	
2.6	Storage of cannabis primary products
EXPORT	
2.7	Export of cannabis primary products
Definitions	

Cannabis bulk: A cannabis product covered by the pilot programme and produced in Denmark. Cannabis bulk products are processed cannabis products that are ready to be processed or to be packed in user-ready packages to become a cannabis primary product.

Cannabis primary product: A cannabis product covered by the pilot programme which is produced in Denmark, and packed as user-ready packages from cannabis bulk.

Issue date: 29.10.2019

Issued by

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Kristine Frederiksen, Medicines Inspector