



Certificate of compliance with Danish legislation on Medicinal Cannabis

On the basis of the inspection carried out by the Danish Medicines Agency on **25.04.2024**, in accordance with section 59 of the Act on a Medicinal Cannabis (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 (no. 1668 of 26/12/2017) and Executive Order on Cannabis Bulk and Cannabis Primary Products (no. 2539 of 14/12/2021).

Certificate no: **DK CBF 10001004**

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 for the subsequent three years following the inspection date. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restriction or Clarification remarks field.

The authenticity of this certificate may be verified by the Danish Medicines Agency.

Type of products subject to inspection

Cannabis bulk
Cannabis primary product

Restrictions or clarification

Activities with Liquids (1.2.1.7) are restricted to storage of retention and reference samples and handling of complaints and recalls only



1.1	CULTIVATION OF CANNABIS
	1.1.1 Cultivation and harvesting
	1.1.2 Drying
	1.1.3 Comminution

1.2	MANUFACTURING
	1.2.1 Cannabis bulk and cannabis primary products
	1.2.1.1 Herbal drug
	1.2.1.7 Liquids
	1.2.2 Batch certification

1.4	Packaging
	1.4.1 Primary packing of Cannabis bulk
	1.4.1.1 Herbal drug
	1.4.2 Primary packing of primary products
	1.4.2.1 Herbal drug
	1.4.2.2 Inhalation vapour, herbal drug
	1.4.3 Secondary packing of cannabis bulk
	1.4.4 Secondary packing of cannabis primary product

1.5	Quality Control Testing
	1.5.1 Physical/chemical

1.7	Other activities
	1.7.1 Export of cannabis bulk
	1.7.2 Export of cannabis primary products



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Definitions

Cannabis bulk: A cannabis product which is produced by a manufacturer with license to produce cannabis bulk 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 which is produced in Denmark, and packed as user-ready packages from cannabis bulk.

Issue date: 09.08.2024

Issued by

Mette Bjørn, Medicines Inspector



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