Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: *NL/H 19/214277A*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***N.V. Organon***
Site address: ***Molenstraat 110, OSS, 5342CC, Netherlands***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***108984 F*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-12-05*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Issued as a true copy by me, Mr. A.G.M. Grundeken,
civil law notary in Oss, the Netherlands.
of the original document, shown and rendered on this,
February 3rd 2020.

Mr. A.G.M. GRUNDEKEN * NOTARIS TE OSS *

Part 2

Human Medici

1 M

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
   This public document
2. has been signed by **mr. A.G.M. Grundeken**
3. acting in the capacity of notary at Oss
4. bears the seal/stamp of aforesaid notary

Certified

5. in 's-Hertogenbosch 6. on 06-02-2020
7. by the registrar of the district court of Oost-Brabant
8. no. 20-354

9. Seal/stamp:

RECHTBANK OOST-BRABANT

10. Signature:

E.J.M. Heijmans

05GH0F

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: hormones(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids 1.1.2.4 Solids and implants Special Requirements 7 Other: hormones(en)
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms Special Requirements 7 Other: hormones(en) 1.2.1.13 Tablets Special Requirements 7 Other: hormones(en) 1.2.1.17 Other: Granules(en) Special Requirements 7 Other: hormones(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products 1.3.1.8 Other: products extracted from urine(en)
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products 1.3.2.8 Other: products extracted from urine(en)
1.5	**Packaging**

	1.5.1 Primary Packing 1.5.1.2 Capsules, soft shell Special Requirements 7 Other: hormones(en) 1.5.1.8 Other solid dosage forms: other(en) Special Requirements 7 Other: hormones(en) 1.5.1.13 Tablets Special Requirements 7 Other: hormones(en) 1.5.1.17 Other non-sterile medicinal products: granules(en)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products

Any restrictions related to the scope of this certificate :

This certificate is valid for the following locations: - Molenstraat 110; 5342 CC Oss; Netherlands - Kloosterstraat 6; 5349 AB Oss; Netherlands;

Clarifying remarks (for public users)

This certificate is valid for the following locations: - Molenstraat 110; 5342 CC Oss; Netherlands - Kloosterstraat 6; 5349 AB Oss; Netherlands;

2019-12-17

Name and signature of the authorised person of the Competent Authority of Netherlands

Drs Gerrit Johannes van Ringen
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