

Ministry of HEALTH, WELFARE and SPORT
CIBG
P.O. Box 16114
2500 BC DEN HAAG
THE NETHERLANDS

No.: 20 155

CERTIFICATE OF A PHARMACEUTICAL PRODUCT¹

This certificate conforms to the format recommended by the
World Health Organization.

(Explanatory Notes and General Instructions attached)

Exporting (certifying) country: **The Netherlands**

No. of Certificate: **20.00640**

Importing (requesting) country: **CHILE**

1. Name and dosage form of product

IMPLANON NXT

68 mg, implant for subdermal use

1.1 Active ingredient(s)² and amount(s) per unit dose³.
For complete composition including excipients see enclosure.

Etonogestrel 68 mg

1.2 Is this product licensed to be placed on the market for use in The Netherlands?⁴

(a) **Yes**

b) application pending **No**

1.3 Is this product on the market in The Netherlands?
Yes

If the answer to 1.2 (a) or 1.2 (b) is yes, continue with section 2A and omit section 2B;
If the answer to 1.2 (a) or 1.2 (b) is no, omit section 2A and continue with section 2B.⁵

2A.1 Number of product licence⁶ and date of issue:

License number: **RVG 21168**

Date of issue: **25-August-1998**

2A.2 Product licence holder (name and address):

N.V. Organon
Kloosterstraat 6
5349 AB Oss,
The Netherlands

2A.3 Status of product licence holder⁷ : a

2A.3.1 Name and address of the manufacturer producing the dosage form is⁸:

MANUFACTURER

N.V. Organon
Kloosterstraat 6
5349 AB Oss
The Netherlands

Steps performed: Manufacturing, packaging, quality control testing and batch release

GAMMA STERILIZATION SITE

Synergy Health Ede B.V.
Morsestraat 3
6716 AH Ede
The Netherlands

Steps performed: Gamma sterilization of finished product in final packaging

ALTERNATIVE SITE for GAMMA STERILIZATION

Synergy Health Ede B.V.
Souvereinstraat 2
4879 NN Etten-Leur
The Netherlands

Steps performed: Gamma sterilization of finished product in final packaging

2A.4 Is summary basis of approval appended?⁹ **No**

2A.5 Is officially approved product information, complete and consonant with the licence, attached? **Yes**¹⁰

2A.6 Applicant for certificate, if different from licence holder (name and address)¹¹:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

3. Does the Netherlands' certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes

3.1 Periodicity of routine inspections (years): **3**

3.2 Has the manufacture of this type of dosage form been inspected? **Yes**

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?¹⁴ **Yes**

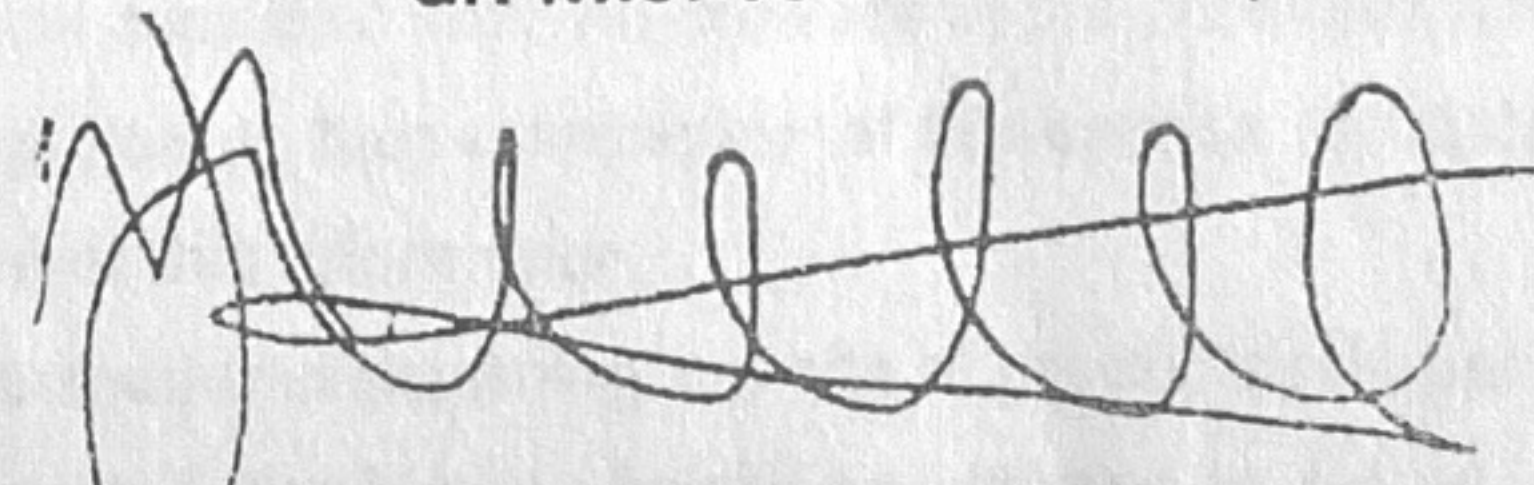
4. Does the information submitted by the applicant satisfy the Netherlands' certifying authority on all aspects of the manufacture of the product¹⁵. **Yes**

Address of certifying authority:

Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC Den Haag, The Netherlands
Tel.: +31 70 340 6624
Fax: +31 70 340 7426

Name of authorized person: **dr. M.J. van de Velde, PhD**

Signature:


Dr. M.J. van de Velde

09 JULI 2020

Stamp and date:





APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
2. This public document
3. has been signed by **dr. M.J. van de Velde**
3. acting in the capacity of Registrar of Medical Professions
4. bears the seal/stamp of the Ministry of Health, Welfare and Sport

Certified

5. in Haarlem
6. on 22-07-2020
7. by the registrar of the district court of Noord-Holland
8. no. 20/ 1577-3

9. Seal/stamp:

10. Signature:

H.T. Sepp - Valpoort



dr. M.J. van de Velde, PhD

Dr. M.J. van de Velde

02 JUL 2020

General Instructions

1. Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme.
2. The forms are suitable for generation by computer. They should always be submitted in type face.
3. Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory Notes

- 1 This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
- 2 Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.
- 3 The formula (complete composition) of the dosage form should be given on the certificate or be appended.
- 4 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is entered into the product licence.
- 5 Sections 2A and 2B are mutually exclusive.
- 6 Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
- 7 Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.
- 8 This information can only be provided with the consent of the product licence holder or, in the case of non-registered products, the applicant. Non-completion of this section (2A.3.1) indicates that the party concerned has not agreed to inclusion of this information.
It should be noted that information concerning the site of production is part of the product licence.
If the production site is changed, the licence has to be updated or it is no longer valid.
- 9 This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- 10 This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)

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- 11 In this circumstance, permission for issuing the certificate is required from the product licence holder. This permission has to be provided to the authority by the applicant.
- 12 Please indicate the reason that the applicant has provided for not requesting registration, e.g.:
- a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export.
 - b) the product has been reformulated with a view to improving its stability under tropical conditions.
 - c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.
 - d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient.
 - e) any other reason, please specify.
- 13 Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
- 14 The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the report of the Thirty-second Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization and are published in the WHO Technical Report Series.
- 15 This section is to be completed when the product licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

ANNEX TO CERTIFICATE OF PHARMACEUTICAL PRODUCT

Name and dosage form of product:

IMPLANON NXT
implant 68 mg

Formula

Etonogestrel*	68 mg
Barium sulfate	15 mg
Ethylene-vinylacetate copolymer (28 % VA)	43 mg
Magnesium stearate	0.1 mg
Ethylene-vinylacetate copolymer (15 % VA)	15 mg

* Active ingredient

ANNEX TO CERTIFICATE OF PHARMACEUTICAL PRODUCT

Name and dosage form of product: IMPLANON NXT
implant 68 mg

The attached SPC conforms to the text approved by the Dutch registration authorities.

2004-10-20

[Signature]

Director General
Dutch Medicines Agency
The Netherlands

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Name and dosage form of product: IMPLANON NXT
implant 68 mg

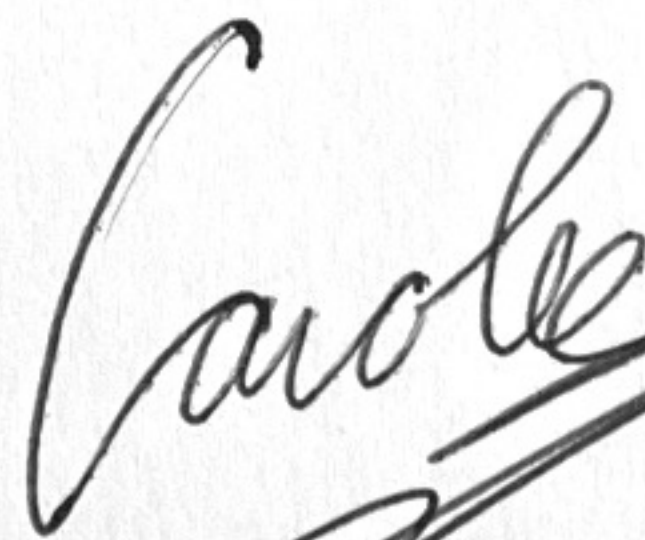
I hereby declare that:

- a) the information in this CPP
- b) the composition as described in the Annex to this CPP and
- c) the English translation of the Dutch SmPC in the Annex to this CPP

reflect the current status in the Netherlands.

N.V. ORGANON

Date: 10 June 2020



Carolien v.d. Wal
Director Regulatory Affairs
The Netherlands

