Guideline on the use of electronic signature verification tools

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Table of contents

Electronic signature 3
How to verify the validity of an e-signature 3
Electronic signature verification with Aruba Sign 4
What is an electronic certificate 5
How the signature process works 6
Annex I: Pages 1-4 of a Certificate of a Pharmaceutical Product with MA granted by AIFA 7

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Electronic signature

An electronic signature (e-signature) is the digital equivalent of a handwritten signature. Just like the latter, it ensures the **authenticity** and **integrity** of a document.

Concerning **authenticity**, the main difference between a handwritten signature and an e-signature lies in the fact that the authenticity of the former is proven by the signatory's handwriting, while the authenticity of the latter is linked to the use of an IT tool ("Smart Card") by the signatory.

Concerning **integrity**, it means that the receiver can be certain that the document has not been altered or modified after it has been signed.

The e-signature is granted by a certifying body (authorised entity) which is responsible for guaranteeing that the signature is secure. In this regard, it should be noted that the certifying body issues a certificate for electronic signature after verifying the applicant's identity.

How to verify the validity of an e-signature

It is possible to immediately verify whether a paper document has been signed just by looking at it. The same applies to an electronic document, although a different procedure should be followed.

After receiving an electronic document, it is necessary to perform a check on its appended signature.

This operation allows to:

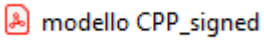
- verify the **signatory's identity**
- verify the **validity** of the signature and the **integrity** of the document, i.e. that its content has not been modified after the signature
- verify that the **certificate for the electronic signature** used is **valid**.

There is a number of (free of charge) software tools that can be used to perform document validation checks, including:

- Digital Signature Service - https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/DSS
- DigitalSign Reader - https://www.comped.it/
- Firma OK! - http://postecert.poste.it/firma/download.shtml
- PkNet - http://www.pksuite.it/ita/pr_pknet_express.php
- DIKE - https://www.firma.infocert.it/
- Firma Certa - https://www.firmacerta.it/
- View2Sign - http://www.andxor.it/prodotti/view2sign.php
- ArubaSign - https://www.pec.it/download-software-driver.aspx

Electronic signature verification with Aruba Sign

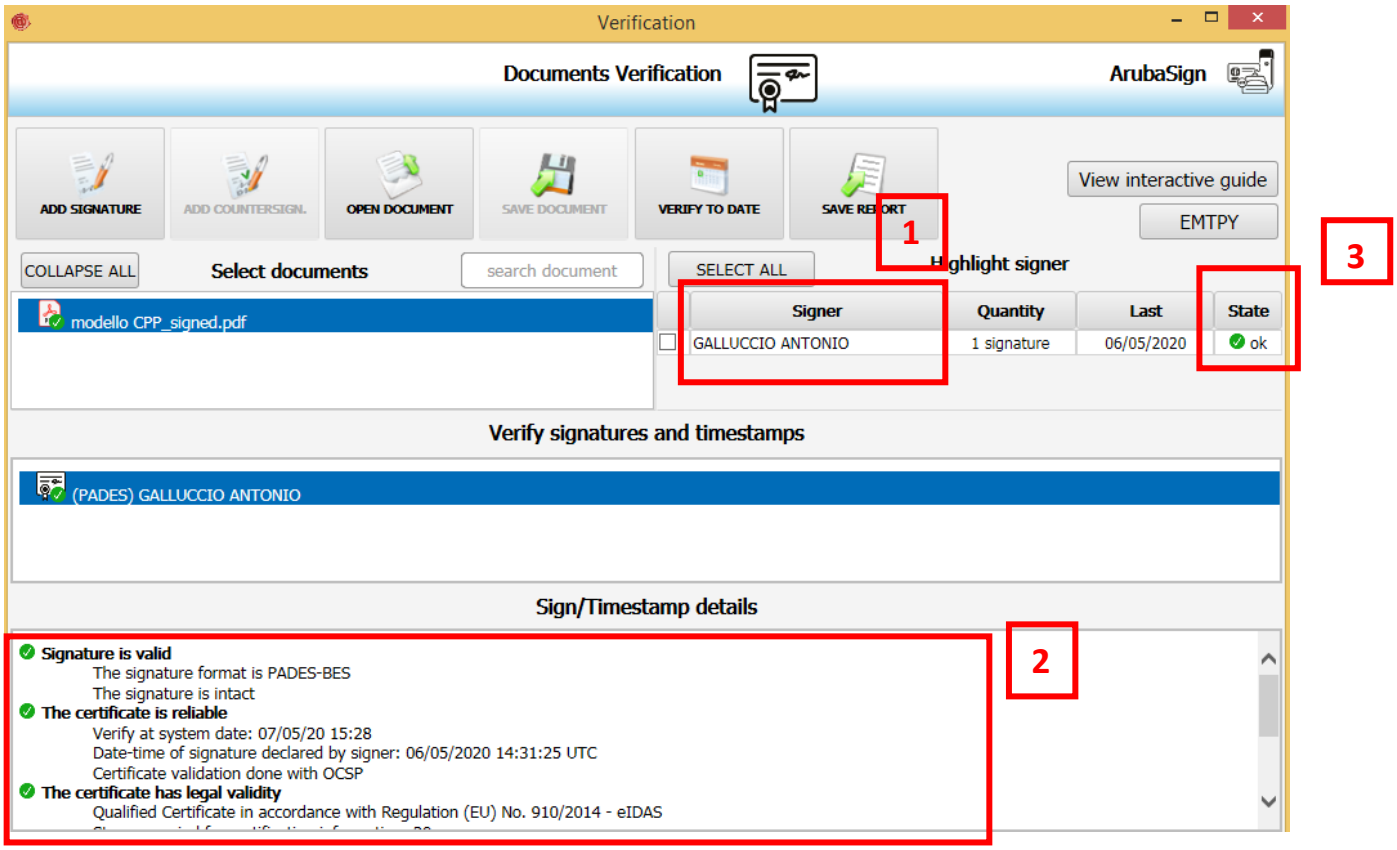
The electronically-signed document is in PDF format and the recipient can immediately verify whether it bears an electronic signature by looking at the file name and, in particular, at the "signed" marker that has been automatically inserted after appending the electronic signature.



To verify the validity of the e-signature, it is necessary to download and install one of the above mentioned software tools.

Subsequently, the file can be dragged and dropped into the "Verify" pane, and all the verification operations can be carried out. These concern the validity of the electronic signature, and include the verification of the signatory's identity and of the certificate's validity.

Once the file has been dragged and dropped in the "Verify" pane, the following window will appear:



Here it will be possible to verify the name of the person 1 who has electronically signed the document, the validity of the certificate 2 and the status of the e-signature 3 .

What is an electronic certificate

An electronic certificate is the complex technology behind an e-signature. However, the technical principles underlying signature and verification can be easily simplified taking into account the user's perspective.

An e-signature certificate can be compared to a well-known tool, a debit card.

A debit card has many features in common with an electronic certificate. In order to have a debit card issued, the requesting person must have their identity physically checked at the bank. Similarly, an e-signature certificate is issued only after the applicant's identity has been verified.

When a signature certificate is granted, the signatory is issued a secret code (PIN) which will be necessary for signing, just like a PIN associated to debit card is necessary to withdraw money.

Just like a debit card, an e-signature certificate has a deadline.

How the signature process works

The signature process is described below.

After a document is drawn up, its content must be made non-editable. This is done by converting the document into a suitable format (e.g. a PDF format) to guarantee its stability and durability over time.

The signatory uses a program to append the electronic signature. The program extracts the document fingerprint, consisting of a string of about 30 characters. The fingerprint uniquely identifies the file, just like a tax code uniquely identifies a person. The e-signature is then appended to the document fingerprint. In this way, an encryption of the fingerprint is created that secures the document.

The result of the e-signature process is an “envelope” containing the signatory’s electronic signature certificate, the signed and non-editable fingerprint of the document and the file in PDF format.

Annex I: Pages 1-4 of a Certificate of a Pharmaceutical Product with MA granted by AIFA

AGENZIA ITALIANA DEL FARMACO

UFFICIO CERTIFICAZIONI E IMPORTAZIONI PARALLELE

CERTIFICATO DI PRODOTTO FARMACEUTICO [1] **CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]**

1.	Esportatore (Paese certificante): *ITALIA* *Exporting (certifying country)*
2.	Importatore (Paese richiedente): XXXXXXXXXXXXX *Importing (requesting country)*
3.	Nome e confezione del prodotto: XXXXXXXXXXXXX compresse rivestite *Name and dosage form of the product*
4.	Principi attivi[2] e quantità per unità di dose[3]: XXX, XX mg *Active ingredient(s)[2] and amount(s) per unit dose[3]*
	Per la composizione completa compresi gli eccipienti[4] si faccia riferimento all'allegato. *For complete composition including excipients, see attached[4].*
5.	Il medicinale è autorizzato per essere commercializzato in Italia SI ☑ NO ☐ *This product is licensed to be placed on the market for use in Italy*
	Il richiedente dichiara che il medicinale è in commercio in Italia SI ☑ NO ☐ *The applicant declares that the product is actually on the market in Italy*
6.	Numero di AIC e data del provvedimento di autorizzazione della confezione: 123456789 del 6 maggio 2020 *Number of product licence and date of the marketing authorization decree*
7.	Titolare AIC (nome e indirizzo): name and address of product license holder *Product licence holder (name and address)*
8.	Status del titolare AIC[5]: c (indicare la categoria come definita nella nota 5) *Status of product licence holder[5]* *(Key in appropriate category as defined in note 5)*
9.	Per le categorie b e c specificare nome e indirizzo del produttore/i responsabile/i per il rilascio dei lotti della forma farmaceutica[6]: name and address *For categories b and c the name and address of the manufacturer(s) responsible for the batch release of the dosage form is/are[6]*
10.	L'autorità certificante effettua ispezioni periodiche nell'officina farmaceutica responsabile per il rilascio dei lotti nella quale la forma farmaceutica è prodotta? SI ☑ Non applicabile [7] ☐ Se la risposta è "non applicabile", non completare le sezioni 11, 12 e 13.

Pratica N° AIN/2020/456 imposta di bollo assolta ai sensi della normativa vigente *Pagina 1*

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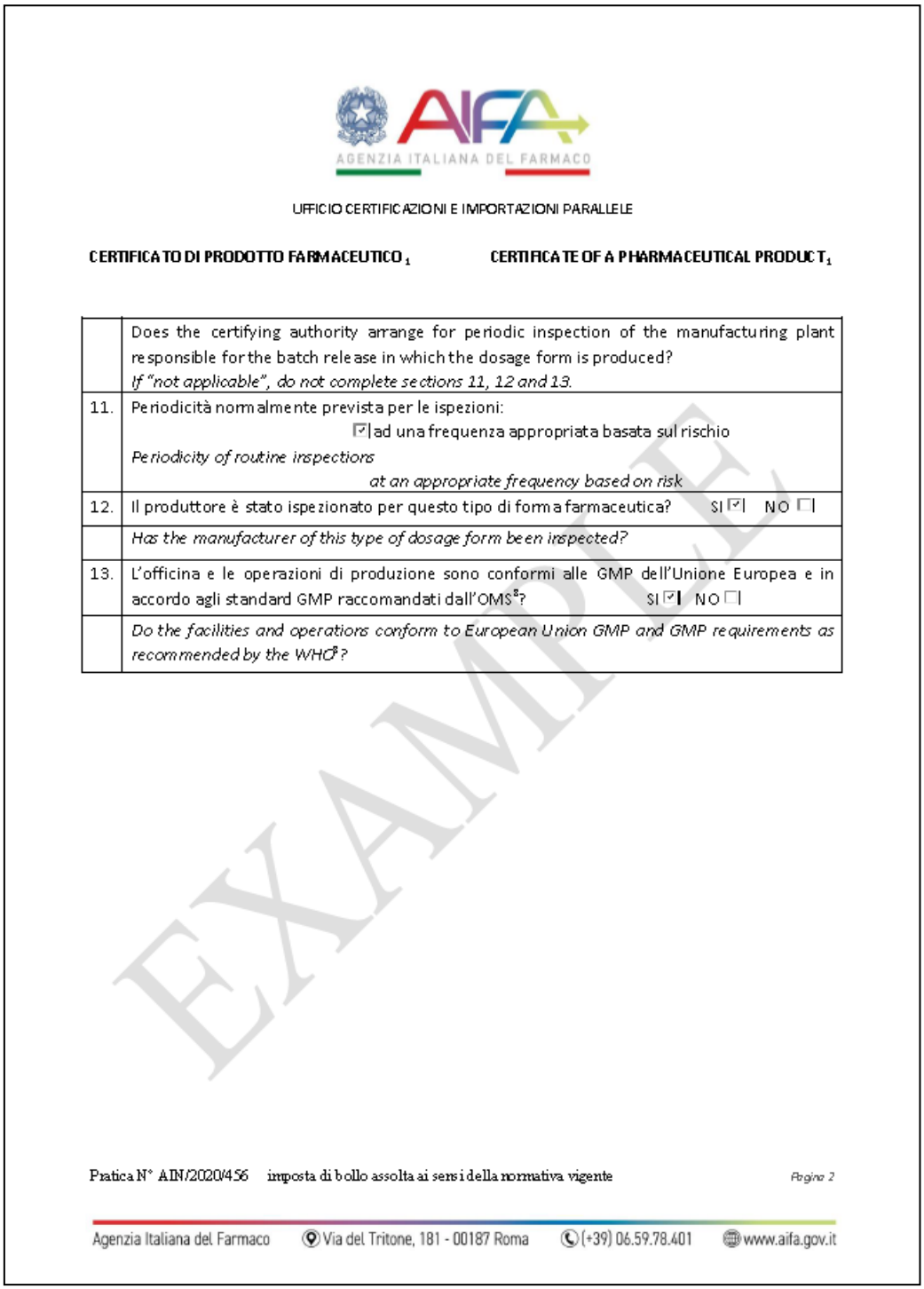

AGENZIA ITALIANA DEL FARMACO

UFFICIO CERTIFICAZIONI E IMPORTAZIONI PARALLELE

CERTIFICATO DI PRODOTTO FARMACEUTICO [1] **CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]**

	Does the certifying authority arrange for periodic inspection of the manufacturing plant responsible for the batch release in which the dosage form is produced? *If "not applicable", do not complete sections 11, 12 and 13.*
11.	Periodicità normalmente prevista per le ispezioni: ☑ ad una frequenza appropriata basata sul rischio *Periodicity of routine inspections* *at an appropriate frequency based on risk*
12.	Il produttore è stato ispezionato per questo tipo di forma farmaceutica? SI ☑ NO ☐ *Has the manufacturer of this type of dosage form been inspected?*
13.	L'officina e le operazioni di produzione sono conformi alle GMP dell'Unione Europea e in accordo agli standard GMP raccomandati dall'OMS[2]? SI ☑ NO ☐ *Do the facilities and operations conform to European Union GMP and GMP requirements as recommended by the WHO[2]?*

EXAMPLE

Pratica N° AIN/2020/456 imposta di bollo assolta ai sensi della normativa vigente Pagina 2

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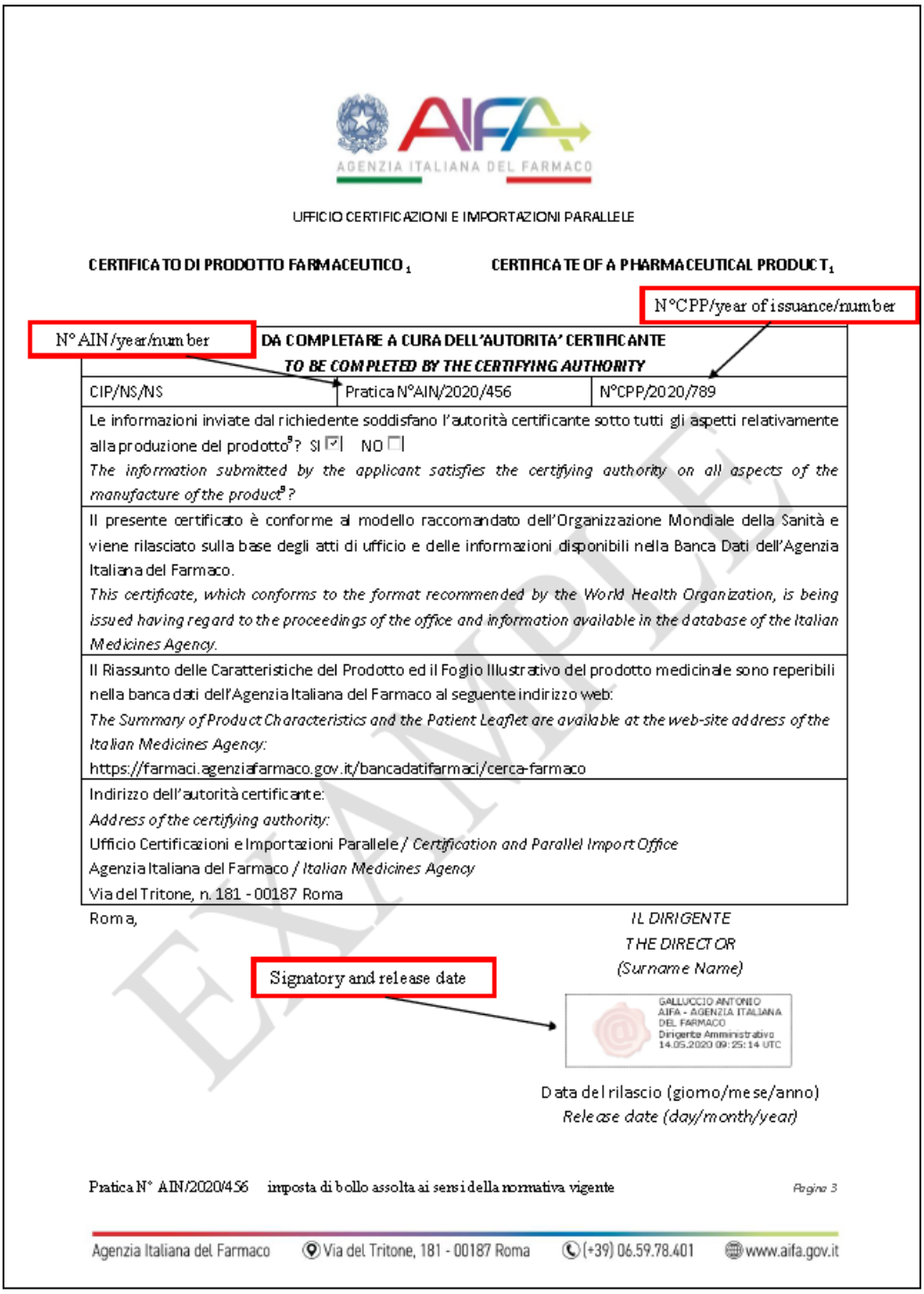

AGENZIA ITALIANA DEL FARMACO

UFFICIO CERTIFICAZIONI E IMPORTAZIONI PARALLELE

CERTIFICATO DI PRODOTTO FARMACEUTICO [1] **CERTIFICATE OF A PHARMACEUTICAL PRODUCT** [1]

N°CPP/year of issuance/number

N° AIN/year/number

DA COMPLETARE A CURA DELL'AUTORITA' CERTIFICANTE
TO BE COMPLETED BY THE CERTIFYING AUTHORITY

CIP/NS/NS	Pratica N°AIN/2020/456	N°CPP/2020/789

Le informazioni inviate dal richiedente soddisfano l'autorità certificante sotto tutti gli aspetti relativamente alla produzione del prodotto[9]? SI ☑ NO ☐
The information submitted by the applicant satisfies the certifying authority on all aspects of the manufacture of the product[9]*?*

Il presente certificato è conforme al modello raccomandato dell'Organizzazione Mondiale della Sanità e viene rilasciato sulla base degli atti di ufficio e delle informazioni disponibili nella Banca Dati dell'Agenzia Italiana del Farmaco.
This certificate, which conforms to the format recommended by the World Health Organization, is being issued having regard to the proceedings of the office and information available in the database of the Italian Medicines Agency.

Il Riassunto delle Caratteristiche del Prodotto ed il Foglio Illustrativo del prodotto medicinale sono reperibili nella banca dati dell'Agenzia Italiana del Farmaco al seguente indirizzo web:
The Summary of Product Characteristics and the Patient Leaflet are available at the web-site address of the Italian Medicines Agency:
https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/cerca-farmaco

Indirizzo dell'autorità certificante:
Address of the certifying authority:
Ufficio Certificazioni e Importazioni Parallele / *Certification and Parallel Import Office*
Agenzia Italiana del Farmaco / *Italian Medicines Agency*
Via del Tritone, n. 181 - 00187 Roma

Roma,

IL DIRIGENTE
THE DIRECTOR
(Surname Name)

Signatory and release date

GALLUCCIO ANTONIO
AIFA - AGENZIA ITALIANA DEL FARMACO
Dirigente Amministrativo
14.05.2020 09:25:14 UTC

Data del rilascio (giorno/mese/anno)
Release date (day/month/year)

Pratica N° AIN/2020/456 imposta di bollo assolta ai sensi della normativa vigente

Pagina 3

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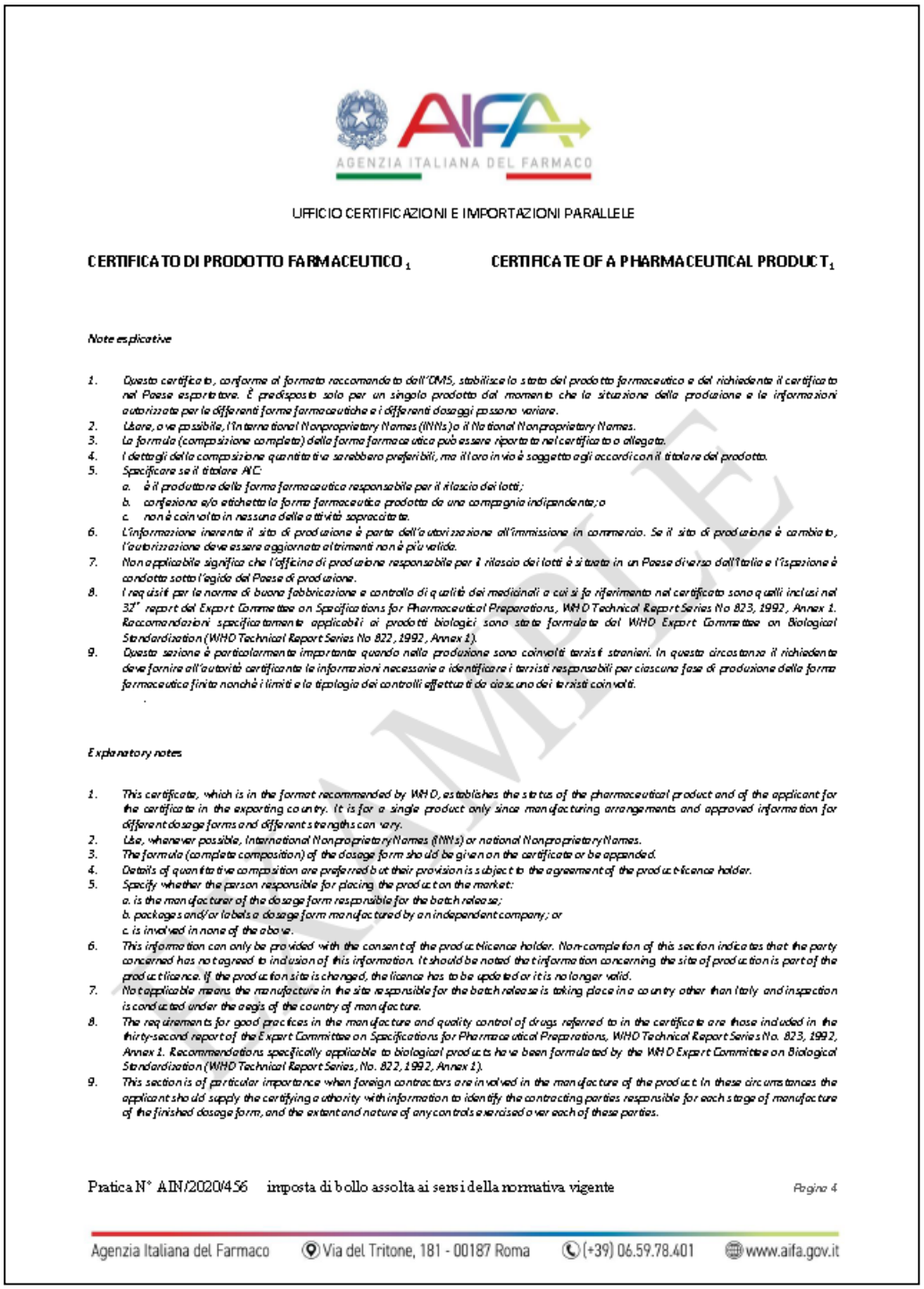

AGENZIA ITALIANA DEL FARMACO

UFFICIO CERTIFICAZIONI E IMPORTAZIONI PARALLELE

CERTIFICATO DI PRODOTTO FARMACEUTICO [1] **CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]**

Note esplicative

1. *Questo certificato, conforme al formato raccomandato dall'OMS, stabilisce lo stato del prodotto farmaceutico e del richiedente il certificato nel Paese esportatore. È predisposto solo per un singolo prodotto dal momento che la situazione della produzione e le informazioni autorizzate per le differenti forme farmaceutiche e i differenti dosaggi possono variare.*
2. *Usare, ove possibile, l'International Nonproprietary Names (INNs) o il National Nonproprietary Names.*
3. *La formula (composizione completa) della forma farmaceutica può essere riportata nel certificato o allegata.*
4. *I dettagli della composizione quantitativa sarebbero preferibili, ma il loro invio è soggetto agli accordi con il titolare del prodotto.*
5. *Specificare se il titolare AIC:*
   a. *è il produttore della forma farmaceutica responsabile per il rilascio dei lotti;*
   b. *confeziona e/o etichetta la forma farmaceutica prodotta da una compagnia indipendente; o*
   c. *non è coinvolto in nessuna delle attività sopraccitate.*
6. *L'informazione inerente il sito di produzione è parte dell'autorizzazione all'immissione in commercio. Se il sito di produzione è cambiato, l'autorizzazione deve essere aggiornata altrimenti non è più valida.*
7. *Non applicabile significa che l'officina di produzione responsabile per il rilascio dei lotti è situata in un Paese diverso dall'Italia e l'ispezione è condotta sotto l'egida del Paese di produzione.*
8. *I requisiti per le norme di buona fabbricazione e controllo di qualità dei medicinali a cui si fa riferimento nel certificato sono quelli inclusi nel 32° report del Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No 823, 1992, Annex 1. Raccomandazioni specificatamente applicabili ai prodotti biologici sono state formulate dal WHO Expert Committee on Biological Standardization (WHO Technical Report Series No 822, 1992, Annex 1).*
9. *Questa sezione è particolarmente importante quando nella produzione sono coinvolti terzisti stranieri. In questa circostanza il richiedente deve fornire all'autorità certificante le informazioni necessarie a identificare i terzisti responsabili per ciascuna fase di produzione della forma farmaceutica finita nonché i limiti e la tipologia dei controlli effettuati da ciascuno dei terzisti coinvolti.*

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. *Details of quantitative composition are preferred but their provision is subject to the agreement of the product licence holder.*
5. *Specify whether the person responsible for placing the product on the market:*
   a. is the manufacturer of the dosage form responsible for the batch release;
   b. packages and/or labels a dosage form manufactured by an independent company; or
   c. is involved in none of the above.
6. *This information can only be provided with the consent of the product licence holder. Non-completion of this section 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.*
7. *Not applicable means the manufacture in the site responsible for the batch release is taking place in a country other than Italy and inspection is conducted under the aegis of the country of manufacture.*
8. *The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).*
9. *This section 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.*

Pratica N° AIN/2020/4536 imposta di bollo assolta ai sensi della normativa vigente *Pagina 4*

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